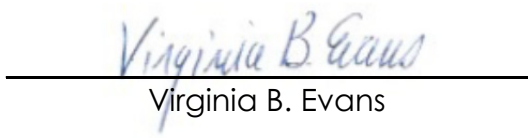
Exhibit 1

U.S. DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

United States of America, *et al.*,	)	
v.	)	Case Number:
Novartis Pharmaceuticals Corporation	)	11 Civ. 0071 (PGG)
	)	

Expert Report of Virginia B. Evans



Virginia B. Evans

AUGUST 14, 2017

Table of Contents

I. Introduction

The United States Attorney's Office for the Southern District of New York engaged me to perform a review of and offer an opinion on the effectiveness of Novartis Pharmaceuticals Corporation's ("NPC") compliance program with respect to certain promotional events called Speaker Programs and Roundtables (collectively, "Speaker Programs") during the period from January 2002 through November 2011, (the "Review Period"). This report summarizes my findings.

A. QUALIFICATIONS

I served for over 25 years as a federal prosecutor, including three years in the Eastern District of New York, and the last 15 years in the District of Maryland where I ran the Health Care Fraud Group and served as Deputy Chief and Chief of the Civil Division. In 2005, I left federal practice for health care consulting, first working for KPMG, and later, for Daylight Forensic & Advisory, LLC. I managed several Independent Review Organization engagements for health care clients under Corporate Integrity Agreements, conducted compliance risk assessments of hospital systems, conducted internal investigations, and worked for Audit Committees and Internal Audit Departments of large health care providers including hospitals, insurers, a national retail pharmacy chain and an international pharmaceutical company.

In 2010, I joined Ober|Kaler as a partner in the Health Law practice focusing on white collar and regulatory defense. I represented health care providers under investigation by the government and expanded my role as a compliance resource for a variety of clients including a pharmaceutical company, several physician practices, laboratories, hospitals and institutional providers. I wrote compliance policies for several of these clients and reviewed policies for others. I also negotiated settlements with state and federal health care agencies in False Claims Act, the U.S. Food and Drug Administration ("FDA") and other health care cases. I represented individuals in health care matters in federal court, before the grand jury and in an exclusion appeal before the U.S. Department of Health and Human Services ("HHS").

In 2012, I relocated to Charlottesville, Virginia, and worked for Centra Health, a four-hospital system as its Vice President, Compliance Officer and General Counsel. The Compliance and Legal Departments were split in early 2015 and I served as Compliance Officer until November 2015 when I left to start my own consulting business.

I am a member of the American Bar Association Health Care Litigation and Risk Management Interest Group, the American Health Law Association, and the Health Care Compliance Association. I am certified in Health Care Research Compliance and am a member of the bar in

New York, Pennsylvania, Maryland, Louisiana and Virginia. My CV is attached hereto as Appendix A.

For my services on this project, I am billing $300 per hour (except for report editing for which I am billing $200 per hour). My compensation is not dependent on my testimony or on the outcome of this case. My work is ongoing and I reserve the right to modify or supplement my conclusions as additional information becomes available to me, or as I perform further analysis.

B. SCOPE OF REVIEW

To gain an understanding of NPC's compliance program during the Review Period, I reviewed deposition testimony and documents and other information produced by NPC. My review included but was not limited to:

- NPC Codes of Conduct, Compliance Policies and procedures, Healthcare Compliance Guidelines, local Working Practice Documents ("WPDs") and standard operating procedures ("SOPs")
- internal e-mails and communications relating to Speaker Programs and NPC's Compliance Program
- organization charts
- reports of compliance breaches and investigations
- compliance training materials
- committee reports and presentation materials
- Speaker Program materials, honoraria payments reports, and information from NPC data collection efforts such as Concerto, Speaker Central, Event Central and Reports Central
- transcripts of depositions of NPC compliance or Speaker Program related witnesses, and associated exhibits
- audit and other internal review reports
- Independent Review Organization and Compliance Expert Reviews
- third party consultant reports
- reports to the Board of Directors and communications to management
- NPC's responses to government discovery requests

A complete list of the information I considered is provided in Appendix B.

C. CRITERIA FOR ANALYSIS

I assessed NPC's Compliance Program using the seven elements of an effective compliance program outlined in the Office of Inspector General of HHS ("OIG"), Compliance Program Guidance for Pharmaceutical Manufacturers (the "OIG Guidance").[1] The OIG Guidance is widely accepted in the healthcare and pharmaceutical industries as setting the foundational practices that should be used to minimize the risk of non-compliance with state and federal laws that are designed to prevent fraud, waste and abuse in Medicare, Medicaid and the other government healthcare programs. I also considered applicable laws and regulations, the Pharmaceutical Research and Manufacturers of America ("PhRMA") Code on Interactions with Health Care Professionals,[2] and the U.S. Sentencing Commission's Sentencing Guidelines for Organizations ("Sentencing Guidelines"), effective on November 1, 1991, and amendments.[3]

The Sentencing Guidelines for corporations are the basis for the compliance guidance promulgated by the OIG and incorporate preventive and deterrent aspects of an effective compliance program. The Sentencing Guidelines outline seven criteria for establishing an effective compliance program:

1. Compliance standards and procedures reasonably capable of reducing the prospect of criminal activity (*e.g.*, a Code of Conduct, compliance policies and procedures);
2. Oversight by high-level personnel (Compliance Officer reporting to CEO and board);
3. Due care in delegating substantial discretionary authority (checks and balances within the organizational structure);
4. Effective communication to all levels of employees (training and education);
5. Reasonable steps to achieve compliance (systems providing for auditing and monitoring, non-retaliation policy, reporting suspected non-compliance, exclusion checks);

---

[1] Department of Health and Human Services, Office of Inspector General, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23732-23733 (May 5, 2003) (the "OIG Guidance").

[2] The Pharmaceutical Research and Manufacturers of America ("PhRMA") Code on Interactions with Health Care Professionals, effective July 2002, accessed August 7, 2017, available at www.ucsfcme.com/physician/PhRMACode.pdf ("2002 PhRMA Code"); PhRMA Code on Interactions with Health Care Professionals, revised effective January 2009, §§ 6-7, accessed August 3, 2017, available at http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf ("2009 PhRMA Code").

[3] See United States Sentencing Commission, Guidelines Manual ("U.S.S.G."), May 1, 2001, Ch. 8, "Sentencing of Organizations," accessed August 8, 2017, at https://www.ussc.gov/sites/default/files/pdf/guidelines-manual/2001/manual/CHAP8.pdf. Archived versions of the various amended Sentencing Guidelines available at https://www.ussc.gov/guidelines/archive (last accessed on August 7, 2017).

6. Consistent enforcement of compliance including discipline; and
7. Reasonable steps to respond to and prevent further similar offenses upon detection of a violation, including appropriate reporting to authorities.

The government will consider the existence and effectiveness of a compliance program when determining whether to charge a corporation with a crime, or alternatively, the court will take an effective compliance program into account and may reduce a sentence by mitigating the potential fine range. Mitigation is contingent upon prompt reporting to the authorities and non-involvement of high-level personnel in the actual offense conduct.[4]

In 2001, the OIG sought recommendations for developing compliance program guidance specific to the pharmaceutical industry to encourage internal controls and to ensure adherence to applicable statutes, regulations and program requirements.[5] The OIG Guidance, which adopted in substance the criteria set forth in the Sentencing Guidelines, was published in May 2003. That Guidance lists seven basic elements fundamental to an effective compliance program:[6]

1. Implementing written policies and procedures;
2. Designating a compliance officer and compliance committee;
3. Conducting effective training and education;
4. Developing effective lines of communication;
5. Conducting internal monitoring and auditing;
6. Enforcing standards through well-publicized disciplinary guidelines; and
7. Responding promptly to detected problems and undertaking corrective action.

The OIG strongly encourages pharmaceutical manufacturers to develop and implement compliance programs tailored to their potential problems, common concerns or high risks. The OIG has identified specific risk areas that are major risks for pharmaceutical manufacturers, including kickbacks and other illegal remuneration.[7]

Promotional events like Speaker Programs create a risk of illegal remuneration. Payments or transfers of value by pharmaceutical manufacturers to health care providers ("HCPs") may trigger

---

[4] *See, e.g.*, United States Sentencing Commission, 2016 Guidelines Manual, Ch. 8, Introductory Commentary, §§ 8B2.1, 8C2.5, accessed August 8, 2017, https://www.ussc.gov/guidelines/2016-guidelines-manual/2016-chapter-8.

[5] OIG Guidance, at 23731.

[6] *Id.* at 23732-33.

[7] *Id.* at 23732.

potential violations under the Anti-Kickback Statute ("AKS") and the False Claims Act ("FCA"). If any one purpose of a payment is to induce an HCP to prescribe medication or refer a patient for treatment covered by the federal health care programs, that payment may violate these laws.[8] This is commonly referred to as the "one purpose rule." The FDA recognizes the benefit of having physicians educate other prescribers about a drug's risks and benefits, however, and requires that presentations promoting a drug be "fair and balanced."[9]

D. EXECUTIVE SUMMARY

Using Speaker Programs as a marketing tool is an inherently risky practice for a pharmaceutical manufacturer because the programs provide remuneration (in the form of meals and/or honorarium payments) to HCPs, who are also prospective customers for the manufacturer's products. In addition, pharmaceutical sales representatives, who typically control many aspects of Speaker Programs, often serving as the event planner and host, are compensated based in part on their ability to meet sales goals, which creates an incentive structure that may lead to the misuse of Speaker Program budgets in ways that violate the AKS and the FCA. Companies that decide to undertake these risky activities should take steps to mitigate and manage these risks by putting in place a robust and effective compliance program.

NPC did not take an enterprise-wide, comprehensive approach to Speaker Program AKS and FCA risk from 2002 until after the Corporate Integrity Agreement ("CIA") was implemented in 2010.[10] For most of the Review Period, NPC's Compliance Program was not risk-based; that is, NPC did not use a regular compliance risk assessment to drive the compliance work-flow, the creation of policies, training, communication, auditing, monitoring and corrective action. Because there was no systematic approach to compliance auditing and no measurement of non-compliance, the policies were uninformed by regular compliance review and they did not effectively address actual Speaker Program risks until 2010. Training was similarly uninformed by the results of auditing and investigations of compliance breaches, and when conducted, did not result in quantifiable compliance improvement or systematic corrective action.

The Compliance Program during the Review Period lacked structure, authority and organization. With respect to Speaker Program risk, the Compliance Department was overly deferential to Sales and Marketing at the expense of compliance objectives. This was reflected in poorly-drafted policies, Speaker Program practices that pushed the boundaries of compliant marketing, compliance communications with mixed messages, the failure to effectively use existing data to

---

8 *United States v. Greber*, 760 F.2d 68, 69-70, 72-73 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985).

9 *See* 2009 PhRMA Code § 6; Federal Food, Drug and Cosmetic Act, 2010 Edition, 21 U.S.C. § 352; 21 C.F.R. § 202.1.

10 *See* OIG-NPC Corporate Integrity Agreement, Sept. 28, 2010, NPCLSV_LIT001009931.

track compliance or to use auditing and monitoring to quantify risk, sporadic and ineffective investigations, inconsistent discipline and inaccurate reporting.

II. Written Policies and Procedures

The OIG Guidance provides that as part of an effective compliance program, pharmaceutical manufacturers should develop and implement written compliance standards, procedures and practices to guide daily operations. The standards should be developed under the supervision of the Compliance Officer, a Compliance Committee and operational managers, and they should be distributed to all employees covered by the policies and any agents or contractors who furnish services having an impact on federal health care benefit programs.[11]

Pharmaceutical manufacturers should develop a core statement of ethical and compliance principles referred to as a "Code of Conduct." The Code of Conduct outlines the organization's fundamental principles and values, and the expectation that employees will be committed to compliance.[12] In addition, a pharmaceutical manufacturer should develop written compliance standards that identify and address specific risk areas.[13] Risk areas are identified internally through a "Compliance Risk Assessment" supplemented by external references, such as the PhRMA Code, OIG Guidance or Fraud Alerts, case law, regulatory developments and agency audit work plans. These policies are typically more detailed than a Code of Conduct and apply to specific types of marketing and other conduct. They should be risk-based and reviewed on a regular basis in the context of additional risks raised by internal and external sources.

Consistent with the OIG Guidance, I sought to determine whether NPC had established standards and procedures that would prevent and detect misconduct including acts in violation of the AKS. I reviewed materials to determine if policies and procedures were risk-based and updated to address new developments about Speaker Program non-compliance. I also assessed whether there was a protocol in place to determine whether the policies needed changing based upon newly-discovered risk or changes to the regulatory landscape.

Finding:

- **NPC did not have effective written compliance standards with respect to Speaker Programs until 2010. Until then, NPC's policies were not risk-based, were vague and ambiguous, and did not address many key Speaker Program risks.**

---

11 OIG Guidance, at 23731, 23733.

12 *Id.* at 23733.

13 *Id.*

A. THE POLICYMAKING PROCESS

The compliance policy development process lacked structure until 2010. From 2002 through 2005, Speaker Program compliance standards were articulated merely as Healthcare Compliance "Guidelines." In 2006, Ethics & Compliance changed the Guidelines to Compliance "Policies" (better emphasizing that they had to be followed). In addition, Compliance lacked an organization-wide, strong decision-making structure until late 2010. Sales Operations and Marketing had their own operating procedures and the business units were fairly independent when it came to written standards, drafting their own Working Practice Documents ("WPDs") and Standard Operating Procedures ("SOPs") which may (or may not) have been reviewed by Compliance.[14]

For most of the Review Period, NPC lacked a "policy about making policies," that is, a formal process for the review, approval and communication of Compliance Policies. Martins R. Putenis, Executive Director of Healthcare Compliance, was primarily responsible for drafting the early Healthcare Compliance Guidelines.[15] Mr. Putenis did not regularly incorporate information from audits, monitoring or investigations into the policies.[16] Without a policymaking procedure in place at NPC, the rollout of new policies was disorganized.[17] For instance, drafts of the 2008 Policies appear to have been circulated from at least January to October of that year,[18] but as late as November 2009, Compliance employees were told at an interdepartmental meeting that a key standard set in that version of policies was still "up in the air."[19] NPC's 2010 policies affirmatively stated for the first time that policies would no longer be developed on an ad hoc basis but would be reviewed annually with each successive version appropriately numbered and dated, driven and maintained by the Compliance Department; the policies further provided that

---

[14] Martins Putenis Deposition 146:5-14, 235:13-236:6; Cynthia Cetani Deposition 52:3-53:20, 53:1-9, 53:12-20, 54:3-9; *see also* IRO Systems Review Report ("IRO Report"), NPCLSV00017962, at 8085 (Cetani Exh. 15), (noting that NPC should consider updating its WPDs and/or business rules to be closer to its actual business practices); 2010 WPD Removal and Reinstatement of Health Care Professionals From Target Lists and Incentive Universes, April 25, 2011, NPCLSV000780592, at 594.

[15] *See* Cynthia Cetani Deposition 88:19-89:10; David Hollasch Deposition 84:2-85:23; Process for Changing HCC Policies, August 2005, NPCLSV_LIT001143216, at 217, ("Novartis lacks an SOP for changing our Healthcare Compliance Policies").

[16] Natalie ("Natasha") Nelson-Ling Deposition 59:4-60:12; David Hollasch Deposition 131:19-132:16.

[17] Natasha Nelson-Ling Deposition 170:22-171:7; David Hollasch Deposition 131:19-132:16, 133:22-136:11.

[18] *See* Draft Ethics & Compliance Policies, January 1, 2008, NPCLSV_LIT003464088; "Ethics & Compliance Policies, Version 1.1" [filename: E&C Policies_May 16 08-FINAL.doc], NPCLSV_LIT000217097; "Ethics & Compliance Policies, Version 1.4," October 2008, NPCLSV00015272 ("October 2008 E&C Policies").

[19] Natasha Nelson email to Eric Kizior, November 6, 2009, NPCLSV_LIT001479754.

any significant changes required circulation of a draft to the Legal Department, Ethics & Compliance Department, business units, and Compliance Committee.[20]

Despite this, it appears that the disorganization persisted. On December 23, 2011, a Navigant compliance expert, Saul Helman, M.D., reported on NPC's 2011 written compliance standards as part of the CIA (the "Navigant Report").[21] Dr. Helman noted that there was no organized policy involving how policies were to be developed or any process for review, approval and distribution of policies.[22] He also observed problems with version control and noted policies were often downloaded by business units and were then superseded by new versions of the same rules causing confusion about which policies were to be used.[23]

Finally, NPC's Compliance Policies were not properly informed by a Compliance Risk Assessment or by data from the field until 2010 when NPC was negotiating and later implementing the above-mentioned settlement. Prior to 2010, the Compliance Department made little use of information available to it from investigations, audits, or other sources to drive policy development.[24] NPC should have reviewed and revised its policies after Speaker Program risks were made clear to management. Its lack of a system or protocol to determine when Compliance Policies needed to be changed weakened its compliance program.

---

[20] Ethics & Compliance Policies, Version 2.0, September 1, 2010 ("2010 E&C Policies"), NPCLSV_LIT000119325 at 421.

[21] *See* Navigant Consulting, Inc., Novartis Pharmaceuticals Corporation, Compliance Program Effectiveness Review ("Navigant Report"), December 23, 2011, Cetani Exh. 16, NPCLSV00017850 at 876; *see also* Ethics & Compliance Policies, May 26, 2011, NPCLSV00014785 ("2011 E&C Policies").

[22] Navigant Report, at 876.

[23] *Id.*

[24] *See* Martins Putenis Deposition 36:2-37:9 (around 2003-2004 no auditing was performed by Ethics & Compliance), 38:3-39:13 (between 1999-2003, auditing of Speaker Programs was under Michael Shaw, who reported to Ann (Harmon) Raffensberger), 41:12-42:4 (monitoring Speaker Program compliance was not a core responsibility of Healthcare Compliance, it belonged to Sales Management), 306:9-24 (Putenis not aware of Nevada audit, not typically informed if audits found violations of speaker program guidelines); 307:12-308:10 (instances of wrongdoing found in an audit were held confidential, Putenis did not have access), 307:23-308:10 (despite having responsibility for training and policy development, Putenis was informed of audit findings in only a general sense or in the form of recommendations), 317:17:-318:2 (Putenis did not receive BPO investigation summaries); David Hollasch email to Julie Kane, "re: NPC Meal Spend Policy," September 30, 2009, NPCLSV_LIT000892661 ("there has been plenty of evidence to demonstrate that current policies and practices are inadequate."); David Hollasch Deposition 134:2-15 (frequent requests for clarification of policies was a signal that the policies were ineffective).

B. SPEAKER PROGRAM POLICIES

OIG Guidance identifies specific risk areas to be addressed in a pharmaceutical manufacturer's policies, including sales relationships with HCPs who can make or influence the referral, ordering or prescribing of drugs paid for by the government. Whenever a manufacturer provides something of value to an HCP who might prescribe the manufacturer's product, the company must consider whether it is providing a valuable, tangible benefit to the HCP with the intent to induce or reward referrals.[25] Because remunerative relationships potentially implicate the AKS, compliance policies should be drafted to detect and prevent AKS and FCA liability.

I consider below NPC's policies[26] as they related to Speaker Program risk and the AKS during the Review Period. Before I do, however, I note a common characteristic of NPC's Speaker Program-related policies was that they were worded so ambiguously that the policies were subject to numerous possible interpretations. Such policies would have therefore been difficult to follow and enforce, a problem recognized by members of NPC's Compliance Department. Natasha Nelson-Ling, an Executive Director in Compliance, testified at her deposition that NPC's policies were "written as a constitution . . . each person had their own interpretation of how they were complying."[27] According to Ms. Nelson-Ling, NPC's policies "were no[t] specific enough" because they used "imprecise language" that "depends upon the interpretation." Ms. Nelson-Ling also "disagreed with many of the sales reps' interpretation[s]."[28] In general, leaving room for subjective interpretation of policies designed to prevent fraud is antithetical to an effective compliance program particularly where interpretation is in the hands of sales representatives or managers who are compensated based on sales or business goals, and thus are incentivized to interpret policies in a sales-friendly manner.

1. Minimum Number of "Legitimate Attendees"

The number of legitimate attendees (*i.e.*, permitted audience members) at Speaker Programs is relevant to AKS risk. It can reflect whether NPC was paying for meals and honoraria incidental to legitimate education about its drugs or using Speaker Programs as pretext for payments to HCPs for other, illegitimate purposes (such as increasing prescriptions or rewarding a high prescriber). The definition of "legitimate attendee" in the context of meeting a minimum audience requirement for Speaker Programs is important for managing the risk that sales

---

25 OIG Guidance, at 23737.

26 In determining which policies to review, I considered the document entitled "Policies Responsive to Rule 30(b)(6) Topics D and E," produced by NPC during the deposition of Julie Kane. *See* Julie Kane Deposition 112:12-113:22, Julie Kane Exh. 6.

27 Natasha Nelson-Ling Deposition 61:14-62:11, 64:17-65:5.

28 *Id.* at 136:4-14, 136:24-137:22.

representatives might include inappropriate attendees in the total head count, thereby defeating the compliance purpose of the minimum attendance requirement. NPC's minimum attendance policy was deficient because before May 2011, there was either no minimum requirement at all or the attendees that NPC counted toward the minimum were not strictly limited to those for whom the educational message of the program was appropriate.

Prior to the 2003 Healthcare Compliance Guidelines, NPC had no requirement for a minimum number of legitimate attendees at Speaker Programs.[29] NPC never imposed a minimum attendance requirement on Roundtables. Starting in 2003, NPC required that there be "at least three healthcare professionals in attendance" at non-Roundtable Speaker Programs, but left the interpretation of "healthcare professionals" up to the sales force.[30] In the 2004 Healthcare Compliance Guidelines, "healthcare professionals" were defined as "those with prescribing rights" but the minimum requirement was loosened by permitting Speaker Programs to proceed without three legitimate attendees if the sales representative had made a "good faith effort" to ensure minimum attendance.[31]

The 2008 Ethics & Compliance Policies modified the attendance rules by changing the "requirement" of at least three prescribers at a Speaker Program to a mere "expectation."[32] While these policies defined a "legitimate attendee" as "[a] participant approved by PRC [the Promotional Review Committee] as a member of an appropriate audience for a specific promotional activity,"[33] Speaker Programs required merely three "prescribers" in attendance per speaker, not three "legitimate attendees."[34] Because "prescribers" could have been in any specialty, including one for whom the educational message of the program was not medically appropriate, this policy did not address the risk that sales representatives would pad attendance numbers. In addition, it appears that even after the 2008 policies were promulgated, Sales and not Compliance determined who was the appropriate audience for a Speaker Programs. Ms. Nelson-Ling noted in a November 2009 email that "[t]he legitimate attendee definition is very up

---

29 *See, e.g.*, Novartis Educational, Promotional & Grant Guidelines ("2001 Guidelines"), NPCLSV00014180, at 200-01.

30 Healthcare Compliance Guidelines 2003, NPCLSV_LIT000369436, Cetani Exh. 2, ("2003 Guidelines"), § 4-1; *see also* Natasha Nelson-Ling Deposition 65:2-5.

31 2004 Guidelines § 5-2, NPCLSV000114745.

32 October 2008 E&C Policies, § 6.05, p. 38 (NPCLSV00015316). The 2006 Guidelines did not change NPC policies concerning attendance at Speaker Programs. See Novartis Ethics & Compliance Policies, January 2006, ("2006 Guidelines"), NPCLSV_LIT001230963. It appears that an interim policy communication addressing attendance was sent to sales representatives in 2006. *See* Julie Kane email to Marty Putenis, Dec. 6, 2006, "Re: Field Confusion over recent policy communications," NPCLSV_LIT000206966.

33 October 2008 E&C Policies, at Appendix A.

34 *Id.* § 6.05; *see also* 2010 E&C Policies § 7.06.

in the air.… In the interim, I was told at the meeting that the 'old' definition would apply *e.g.*, Sales Management can decide who they want reps to target and that is sufficient."[35] Only in NPC's May 2011 policies, was the "expectation" of a minimum number changed back to a "requirement," and rather than requiring three "prescribers," Speaker Programs were required to have three "legitimate attendees," defined as "any individual on the list of MAP-approved audience members for whom the presentation is professionally relevant."[36]

In sum, while NPC policies required a minimum of three attendees for Speaker Programs beginning in 2003, because of the loose and changing definition of who could be counted as an attendee and because of assignment of that determination to the sales force (who were incentivized to keep prescribers happy), for a long time this policy did not have real "teeth." Until 2011, NPC's minimum attendance policy for Speaker Programs was not effective at managing the risk that promotional events could be used to provide payments to HCPs for illegitimate purposes.

2. Policy Regarding Guests

The PhRMA Code provides that modest meals at Speaker Programs are considered a business courtesy necessary to impart information leading to improved patient care.[37] There is no legitimate business reason for a pharmaceutical company to provide meals to spouses or other guests of attending HCPs if those guests are not themselves the intended audience for the medical information. This practice directly implicates anti-kickback concerns because meals provided to guests constitute a benefit or gift conferred on the HCP.[38] NPC's compliance policies did not control this risk because until 2008, they did not prohibit spouses and guests from attending Speaker Programs.

NPC's 2001 and 2003 Guidelines contained no general prohibition against a guest or spouse attending a Speaker Program,[39] and there is evidence NPC regularly allowed spouses to attend at that time.[40] While an intervening brochure created in 2002, "The PhRMA Code, Novartis &

---

35 Natasha Nelson email to Eric Kizior, November 6, 2009, " Re: IMPORTANT: New information on sign in sheets," NPCLSV_LIT001479754.

36 2011 E&C Policies § 7.6, p. 41. The Material Approval Process ("MAP") was developed in 2010 and outlined in the 2010 E&C Policies, at § 2.

37 2009 PhRMA Code, at p. 4; 2002 PhRMA Code, at p. 2.

38 2009 PhRMA Code, at p. 5; 2002 PhRMA Code, at p. 8; *see also* David F. Essi, "Mixing Dinner and Drugs—Is it Ethically Contraindicated?" *American Medical Association Journal of Ethics* 17(8) (August 2015), 787-795, accessed June 25, 2017, available at http://journalofethics.ama-assn.org/2015/08/sect1-1508.html.

39 2001 Guidelines, at NPCLSV00014200; 2003 Guidelines § 4-1.

40 *See, e.g.*, Martins Putenis e-mail to Bob Doyle, February 8, 2002, NPCLSV_LIT003294683.

You," discouraged spouses from attending Speaker Programs and advised that if a spouse attended, the consultant (*i.e.*, the speaker) should be asked to pay for the spouse's meal, it did not prohibit guests nor address how to respond to the presence of the spouse or guest of an attendee (rather than a speaker).[41]

From 2004 to 2008, NPC policies prohibited sales representatives from *inviting* spouses and guests to promotional events but if they showed up, sales representatives were not required to turn them away but instead were to remind the HCP "of Novartis policy and advise . . . of our expectation that policy will be adhered to in the future."[42] NPC did not require sales associates to insist that guests or spouses leave the meeting until 2008.[43] This created a loophole through which sales associates could provide benefits to HCPs with no consequences.

3. Repeat Attendance

During the Review Period, NPC's Compliance Policies failed to control for a serious AKS risk—that an HCP (or a group of HCPs) would repeatedly attend events about the same drugs, including long after those events stopped having educational value for that HCP. NPC never restricted the number of times a single HCP could attend events and thus never mitigated the risk that the same HCPs could be repeatedly provided something of value (meals and/or honoraria) at an event without an educational component.

In its 2003 Healthcare Compliance Guidelines, NPC permitted sales representatives to give modest meals to an HCP on no more than an "occasional basis."[44] However, at no point during the Review Period did NPC define "occasional" or attempt to limit repeat attendance by the same HCPs at events.[45] Nor was it even clear that the "occasional" restriction was even intended to apply to Speaker Programs.[46] Failure to define "occasional" allowed sales associates to invite the same HCPs out to dinner to hear about the same drug (sometimes from the same speaker)

---

41 The PhRMA Code, Novartis & You, NPCLSV00014306, at 317.

42 2004 Guidelines § 5-7. There is no mystery as to why NPC continued to allow spouses and guests to attend Speaker Programs. An NPC PowerPoint presentation dated August 2004 discussing industry trends stated that "[s]ince the PhRMA Guidelines were enacted in 2002, 'spouse/guest not invited' has increased as a major reason why physicians are declining events." *See* Novartis "Meetings & Events Project Team Status Update," August 2004, NPCLSV_LIT002102717, at 733.

43 October 2008 E&C Policies, at p. 38. This policy did not materially change for the rest of the review period. *See also* Novartis Ethics & Compliance Policies, Version 1.5, Updated June 25, 2009 ("2009 E&C Policies"), NPCLSV00015362, at p. 38; 2010 E&C Policies, at p. 46; 2011 E&C Policies, at p. 42.

44 2003 Guidelines § 4-3 (NPCLSV_LIT000369451).

45 See NPC's Supplemental Responses and Objections to Plaintiff's Notice of Deposition under Fed. R. Civ. P. 30(b)(6), March 10, 2017, ("NPC Supplemental Responses 3/10/2017"), at p. 20.

46 Julie Kane Deposition 97:4-98:8.

multiple times in a single year. Given sales associates' incentives to please HCPs—their customers—this lack of definition created the risk that associates would adopt a "gaming" mentality.[47] Indeed, the event data produced by NPC in this case shows that repeat attendance happened throughout the Review Period.[48]

It also appears from documents and witness testimony that NPC considered some repeat attendance to be positive for its business.[49] But, in my opinion, it is also clear from the materials that NPC was aware that repeat attendance presented serious compliance risks.[50] In addition, there is evidence that NPC knew that sales representatives were repeatedly organizing Speaker Programs with the same groups of HCPs in a manner suggestive of illegal activity.[51] Nonetheless,

---

[47] *See* Polaris Management Partners 2004 Report, "Targeting and Incentives" Binder, NPCLSV_LIT003315304, pp. 6-13 (NPCLSV_LIT3315309 to NPCLSV_LIT3315316); "Novartis IV 3T 2004 INCENTIVE PLAN, Sales Representative, Level One," NPCLSV_LIT001443898; "1T04 Field Analysis Update: Incentive & Targeting Plans," letter addressed to Field Force Associates, NPCLSV_LIT001228309; "Coaching the Incentive Program," Field Line Manager Workshop, 2010 CV Incentives Strategy, NPCSLV_LIT003194782; see also Karen Sorenson Deposition 211:6-20 (sales representatives knew how to "game" the NEC system to add inaccurate information).

[48] *See* Expert Report of Richard E. Goldberg.

[49] *See* NPC Supplemental Responses 3/10/2017, at p. 20; Julie Kane Deposition 50:8-51:24, 52:8-53:1, 275:16-276:3, 278:15-279:3; Cynthia Cetani Deposition 33:9-36:1.

[50] *See* "Ethics & Compliance" brochure, NPCLSV_LIT006274542, at 544 (including a list of "Do's and Don'ts" including "Do not hold meetings on a reoccurring basis"); *see also* Natasha Nelson-Ling Deposition 196:4-197:10 (repeat attendance presented anti-kickback; David Hollasch Deposition 240:10-243:10 (FLMs directed to check whether the same speaker/participants attended repeatedly, going to an excessive number of programs is inappropriate); Cynthia Cetani email to David Hollasch and preceding email chain, April 17, 2009, NPCLSV_LIT006612017 (Hollasch Exh. 10), at 020 (discussing revisions to the FLM dashboard and noting that repeat attendance would not comply with occasional meals policy, so frequent participation should be reviewed); "Questions Received at National Manager's Meeting," December 12-13, 2007, NPCLSV_LIT006868844, at 854 (NPC policy required that meals with HCPs be no more than "occasional" but NPC has "chosen to leave the determination of 'occasional' up to the representative in consultation with his/her manager"); Maria Woods email, July 31, 2007, NPCLSV_LIT001153637 (attaching notes on BPO 46/2007 stating that employee "appears to have hosted the same individuals repeatedly at the same topic/presentations problematic because it creates the appearance of providing honoraria to speakers for illegitimate programs (kick-back issue)").

[51] *See* Corporate Security Investigation Report: Alleged Fraud in the Toms River POD, BPO Case 71-2007 & BPO Case 581-2007, May 8, 2008, NPCLSV_LIT003461575; Michael Shaw email, February 23, 2006, re: "Electronic Cafepharma posting," NPCLSV_LIT000203831; Dorothy Watson email, January 13, 2008, re: "Novartis reps claim speakers programs gone wild," NPCLSV_LIT003598725; Natasha Nelson email, June 18, 2009, re: "CafePharma postings re: Novartis speaker program abuse," NPCLSV_LIT000215324; Mark Hennion email to John Repsha, December 20, 2007, re: "BPO 550/2007," NPCLSV_LIT002616100 (forwarding August 17, 2007 email from Stephen Kanovsky, Compliance Officer at Sanofi-Aventis, to Julie

Continued on next page

NPC's Compliance Policies never included a limit on the number of events a single doctor could attend.[52] I found no evidence of an attempt to modify NPC's policies to address the significant anti-kickback risk posed by repeat attendance—that sales associates would hold promotional events repeatedly with the same HCPs who were not gaining educational value from the events but merely enjoying remuneration in the form of meals (and honoraria).

4. Venue and Entertainment Policies

Sales representatives' interactions with HCPs are permitted under the PhRMA Code when they are professional in nature and intended to facilitate exchange of medical or scientific information that will benefit patient care.[53] Entertaining healthcare professionals serves no legitimate business purpose in this regard and is purely remunerative.[54] NPC Speaker Program policies did not properly manage the risk of conferring this kind of benefit on HCPs because entertainment was permitted for some types of events until 2008 and because sales representatives were allowed to apply their own judgment to determine whether certain venues were appropriate for Speaker Programs.

In 2001, NPC permitted entertainment if "the educational portion of the program" received greater emphasis than "the non-educational portion" and sales representatives scheduling events used "good judgment . . . when planning program social events."[55] NPC's decision to permit sales representatives to exercise their judgment about appropriate entertainment when their compensation was based upon the volume of drugs prescribed by attending HCPs was a poor way to control anti-kickback risk.

Beginning in 2003, NPC's Healthcare Compliance Guidelines incorporated language from the PhRMA Code that promotional events should be held at "venues conducive to an exchange of medical information"[56] but also allowed "modest" entertainment such as golf after a full day of

---

Continued from previous page

Kane, raising possible compliance issues at "Field based activities"); David Hollasch Deposition 261:15-265:3; Natasha Nelson-Ling Deposition 139:6-140:12, 146:6-148:23, 254:22-256:12.

52 *See* NPC Supplemental Responses 3/10/2017, at p. 20.

53 *See* 2002 PhRMA Code, at p. 2 (relationships with HCPs are intended to benefit patients and to enhance the practice of medicine), p. 7 (provision of entertainment and recreational activities is inconsistent with the Code); 2009 PhRMA Code § 3 (Prohibition on Entertainment and Recreation).

54 *See* OIG Guidance, at 23738; PhRMA Code, Novartis & You, October 2002, NPCLSV00014306, at 310.

55 2001 Guidelines, at p. 22, (NPCLSV00014201); *see also* Putenis e-mail to Laura Perkins, February 25, 2002, "Re: Lotrel CEP Program Approval - Basketball, Memphis Grizzlies," NPCLSV_LIT001133701 (approving Speaker Program during NBA basketball game).

56 2003 Guidelines §§ 4-1, 4-3; 2004 Guidelines § 5-2; 2006 Guidelines, at p. 48; October 2008 E&C Policies, at p. 39 (NPCLSV00015317); Novartis Ethics & Compliance Policies, Version 1.5, June 25, 2009,

Continued on next page

consulting such as a lengthy speaker training event.[57] Later NPC policies provided modest entertainment may be appropriate if approved by the Events Oversight Committee.[58] The rationale supporting these exceptions to the no-entertainment rule is unclear. Only in 2008 did NPC policy preclude holding all events in conjunction with entertainment or a recreational event.[59]

Finally, NPC should have developed specific policies and controls to ensure Speaker Programs only took place in appropriate venues. Such venues should be quiet and private enough (and with appropriate audiovisual equipment and presentation space) for communication of educational information and not lavish or otherwise suggestive that they were a reward or perk for prescriber loyalty.[60] Instead, NPC generally left determination of what venues were appropriate up to sales representatives.[61] And except for a brief period in 2006, when NPC attempted to limit the use of venues considered "extravagant" by prohibiting the use of Ruth's

---

Continued from previous page

NPCLSV00015362, p. 39, (NPCLSV00015406); 2010 E&C Policies, p. 46 (NPCLSV_LIT000119378); 2011 E&C Policies, p. 42 (NPCLSV00014840).

57 2003 Guidelines, § 4-3 (NPCLSV_LIT000369451). Starting in 2008, NPC's Compliance Policies limited appropriate venues for speaker training meetings to "marketing research facilities, reasonable business hotels, and Novartis offices" and excluded "resorts, lavish hotels, dinner cruises, sports facilities, comedy clubs, and casinos." *See, e.g.*, October 2008 E&C Policies, § 4.11, p. 31 (NPCLSV00015309) (giving examples of appropriate and inappropriate venues), § 5.07 (applying venue rules for Advisory Boards to speaker trainings); Novartis Ethics & Compliance Policies, Version 1.5, June 25, 2009, NPCLSV00015362, p. 31 (NPCLSV00015398); 2010 E&C Policies, p. 38 (NPCLSV_LIT000119370); 2011 E&C Policies, p. 34 (NPCLSV00014832).

58 2004 Guidelines § 5-4; *see also* 2006 Guidelines, at p. 34 (NPCLSV_LIT001231002), p. 43 (1011), p. 45 (1013), 48 (1016), 49 (1017), 74 (1042); Event Oversight Committee "EOC" Standards, Cindy Cetani, Director, Ethics & Compliance, July 26, 2006, NPCLSV_LIT000762076 (July 2006 presentation stating "some [entertainment] possible with lengthier meetings.").

59 October 2008 E&C Policies §§ 4.15, 5.07, 6.07.

60 NPC appreciated the importance of having events in private rooms early in the Review Period. *See, e.g.*, undated "Speaker Program & Roundtable Best Practices" protocol list, NPCLSV_LIT001358682 (sent to Cynthia Cetani via April 2004 email, NPCLSV_LIT001358680), stating "[s]elect either a restaurant or hotel with a private room large enough to accommodate your meeting. Private rooms by definition, have four walls. A restaurant that divides a larger public eating space with a wall of potted plants is not an appropriate venue for proprietary medical discussions." A draft of a standard contract between NPC vendor AHM and restaurants hosting speaker programs provided "a private room is preferred" but not required. See AHM/Novartis "Food & Beverage Service Agreement," NPCLSV_LIT000952706, at 708. The requirement of a private room should have been incorporated into the Compliance Policies.

61 *See* Cynthia Cetani Deposition 58:16-62:3; Julie Kane Deposition 88:6-90:24.

Chris and Morton's Steakhouses for Speaker Programs,[62] NPC's policies did not limit the use of any particular expensive restaurants. After the sales force complained about the Ruth's Chris and Morton's restriction, it was reversed.[63] Given the frequency of violations of modest meals policies (described further below), NPC should have prohibited representatives from hosting events at "high end" restaurants where meals were generally not "modest."[64]

5. Modest Meals and Aggregate Spend Policies

Providing meals to physicians is only acceptable under the PhRMA Code if the speaker meeting is designed to impart scientific and clinical information about a manufacturer's products that may lead to improved patient care and the meal is modest by local standards.[65] Until 2008, NPC's "modest meals" policies were so poorly drafted that they failed to minimize the compliance risks in providing meals to prescribers.

NPC's early policies, while permitting only "modest" meals, failed to define "modest," and thus did not limit sales representatives who were motivated to use lavish meals as perks to keep their prescribers happy. In 2004, NPC defined "modest" by providing that meals outside of the office be capped at $125 per person for urban areas and $80 to $100 per person in other areas,[66] but did not address the practice of splitting bills to circumvent this restriction until 2008.[67] (This cap was later changed to $125 per person regardless of geographic area.[68])

6. Honoraria Amounts

The payment of compensation to an HCP for services as a speaker implicates the AKS because payments may induce or reward prescription behavior.[69] If one purpose for paying an HCP is to

---

[62] *See* Julie Kane email to Marty Putenis, Dec. 6, 2006, "Re: Field Confusion over recent policy communications," NPCLSV_LIT000206966, and preceding email chain.

[63] *See* Julie Kane Deposition 215:17-216:17, 218:13-24, 219:11-17, 219:25-220:4, 222:2-13 (discussing NPCLSV_LIT006588864 (Kane Exh. 13)).

[64] *See* Martins Putenis email to Cynthia Cetani, May 29, 2007, NPCLSV_LIT000922578 ("We don't at this time prohibit reps from using other high end restaurants as long as they can stay within our modest meals guidelines.").

[65] 2002 PhRMA Code § 2.

[66] 2004 Guidelines §§ 3-4, 3-5.

[67] October 2008 E&C Policies, at p. 39 (NPCLSV00015317); *see also* 2010 E&C Policies § 7.09.

[68] October 2008 E&C Policies, at p. 39 (NPCLSV00015317).

[69] OIG Guidance, at 23737, 23738; *see* "A Practitioner's Primer on the History and Use of the Federal Anti-Kickback Statute", Marc S. Raspanti and Douglas E. Roberts, American Health Lawyer Connections, March 2017, p. 16, at 19; http://www.pietragallo.com/library/files/msr,_der_-

Continued on next page

induce future prescribing or to reward for past prescribing, the statute has been violated.[70] It is therefore important that professional services arrangements be in writing, that there be a bona fide business purpose for the arrangement, that the services be performed and the compensation paid be documented, and that the compensation be no more than fair market value ("FMV").

NPC's policies were insufficient to manage this risk because for much of the Review Period, NPC did not ensure that HCPs were paid fair market value for speaking services. NPC's Guidelines contained no mention of fair market value at all until 2003.[71] After this time, the policies refer to "fair market value" but NPC based its value assessment of speaker services on historic payments to HCPs.[72] During this time period, the fair market value per specialty in each geographic region

---

Continued from previous page

_a_practitioners_primer_on_history_and_use_of_federal_anti-kickback_statute.pdf; accessed August 9, 2017.

70 The AKS addresses the possibility that when a person who is in a position to control from where a Medicare patient purchases an insured item or service, is paid for that referral, not only will the medical referral decision not be made with the patient's best interests in mind, but the overall cost of healthcare will be driven up by the payment of referral fees and by the referral of patients for care they do not need. *See* "Prosecuting and Defending Health Care Fraud Cases," Michael K. Loucks and Carol C. Lam, The Bureau of National Affairs, Inc., Washington, D.C. (2003), p. 146-148. Compensation in excess of fair market value for services provided is not "commercially reasonable" and therefore raises AKS concerns. *See* 42 C.F.R. §§ 1001.952(d)(5), (d)(7); *see also* OIG Guidance, at 23737.

71 2001 Guidelines, at NPCLSV00014186 (merely indicating "modest honorarium"); 2003 Guidelines, at § 3-1 (NPCLSV_LIT000369444) (referencing "fair market value" only in the context of warning that a payment or other benefit may violate the AKS if "an honorarium . . . is greater than fair market value," but providing no further guidance); *see also* 2004 Guidelines § 1-2; 2006 Guidelines, at p. 3 (fair market value for honoraria in context of AKS). Beginning in around 2008 or 2009, the Policies began to reference fair market value in the sections directly discussing Speaker Programs. *See* October 2008 E&C Policies § 5.06 (honorarium for speaker training attendance "must not exceed fair market value") § 6.09 (speakers "must not receive compensation exceeding fair market value"); Ethics & Compliance Policies, Version 1.5, updated June 25, 2009, NPCLSV00015362 § 5.06 (honorarium for speaker training attendance "must not exceed fair market value") § 6.09 (speakers "must not receive compensation exceeding fair market value").

72 Cynthia Cetani Deposition 222:11-224:7 (fair market value calculation up through at least 2007 did not involve Ethics & Compliance and was based on historic data of honoraria previously paid); *see also* Novartis Internal Audit, Operations Audit Report, "NPC Meetings and Events: August 6 to 24, 2007," Report No. 2007/46, NPCSLV_LIT000751260 (Cetani Exh. 7), at 267) ("[h]onoraria for sales executed events is suggested by the field force representatives based on historical data . . . and is approved by the relevant district manager"); Schofield email to Meena Nayar, September 19, 2003, NPCLSV_LIT001995283 (Schofield Exh. 2) (comparison of what NPC was paying speakers as opposed to competitors from about 2001 through 2003); Gregory Schofield Deposition 84:12-20, 93:23-94:6, 101:16-102:14, 107:6-11; David Hollasch Deposition 294:4-295:22 (expressing concern that criteria for speaker selection and honoraria tier system were not specific or measureable and could lead to misclassification).

was easily calculable using third party vendors or standard valuation methodology.[73] NPC documents show that the organization recognized that this was the best practice early on but was slow to implement it.[74] Only in 2008 did NPC begin trying to peg honorarium amounts to fair market value by using AHM to review speaker CVs and place HCPs into one of four tiers associated with an honorarium amount based on "benchmarking data . . . received from multiple speaker management vendors."[75]

In addition, the total amount of speaker payments per HCP should have been capped each year as advised in the PhRMA Code.[76] NPC was aware of potential risks in paying speakers excessive amounts of honoraria—excessive HCP spend was a concern mentioned in internal discussions as early as 2003,[77] and identified in NPC's policies and internal documents as a risk.[78] While NPC did impose some annual honoraria caps for state law purposes in 2005, and implemented system-

---

[73] *See, e.g.*, Medical Group Management Association, accessed July 25, 2017, www.mgma.com/industry-data/mgma-surveys-reports (website landing page for a service which will provide compensation information for medical consulting services for specialties in a geographic area).

[74] *See* Michael Shaw email to Marty Putenis & Maria Woods, Sept. 11, 2006, NPCLSV_LIT000819189 (attaching presentation "from Polaris that may offer some helpful considerations as you develop our recommendations for FMV methodology"); Melissa Dannenfelser email to Maria Woods, et. al, Oct. 25, 2006, NPCLSV_LIT007212685; Maria Woods email to Beth Margerison, March 13, 2007, NPCLSV_LIT001188166 (attaching documents from 2004 discussing fair market value methodology); Speaker & Event Management Outsourcing Request for Final Direction of Project, May 2007, NPCLSV_LIT000899861, at 863 ("Honoraria costs will improve with FMV policy implementation"); Martins Putenis 2007 Annual Performance Review, NPCLSV_LIT012425796, at 798 ("Intervened to re-ignite efforts in this area; FMV recommendations recently approved by Senior Management."); Frank Arena email to Kay Roelke, Sept. 14, 2007, NPCLSV_LIT006385827, at 828 (Kay Roelke writes "[e]xcessive honoraria should go away in 2008 with FMV").

[75] Michael Shaw email to Ann Bacon, July 23, 2008, NPCLSV_LIT000395829, and attachment, NPCLSV_LIT000395834 (non-oncology HCPs paid $1000, $1500, $2000 or $2500 per live Speaker Program depending on tier); Fair Market Value: Promotional Speakers & Promotional Events, Sept. 17, 2007, NPCLSV_LIT006830701; Frank Ramirez email to Anthony Ortiz, *et al.*, Nov. 2, 2007, NPCLSV_LIT002865104 (sales associates informed "[y]ou will no longer negotiate with the speaker his/her honorarium").

[76] 2009 PhRMA Code § 7; *see also* "PhRMA Strengthens Marketing Code on Interactions with Health Care Professionals," July 2008, NPCLSV_000907048.

[77] A 2003 draft outlining discussions leading up to NPC's 2004 Healthcare Compliance Guidelines provided "No individual Speaker should be used so frequently that the aggregate compensation to the Speaker in a single year would 'cause a reasonable party' to ['lawyer speak!'] question his or her objectivity as a Health Care Professional." Novartis Speaker Bureau Policies and Guidelines, July 20, 2003, NPCLSV_LIT006408894, at 899.

[78] *See, e.g.*, 2004 Guidelines §§ 1.1, 1.2; 2006 Guidelines, at p. 3 (NPCLSV_LIT001230971); October 2008 E&C Policies §§ 5.06, 6.06.

wide honoraria caps and thresholds in 2006,[79] it permitted speakers to exceed their caps for business purposes.[80] For example, in August of 2007, NPC allowed six speakers to exceed their $125,000 cap to use them to promote a new product called Exforge. Company executives expressed concern that if NPC could not pay them, the HCPs would be targeted for recruitment by other pharmaceutical companies and this would put NPC at a competitive disadvantage.[81] NPC's policy of capping remuneration was also deficient because, until 2010, only compensation for the actual speaker event itself counted towards the cap, not any other payments made to the speaker, such as payments for attending speaker training.[82]

7. Speaker Selection and Performance

Because selection as a speaker can result in a substantial financial benefit for a prescribing HCP, it raises a high risk of AKS violation. Speaker selection criteria should therefore be based on the educational reason for the program.[83] Speaker selection should be based on medical expertise directly related to the subject drug or condition, and individuals making speaker selections should themselves be qualified to judge the medical expertise of potential speakers.[84] The number of speakers should be limited to those necessary to convey the information sought.[85] And speakers' performance should be evaluated to determine whether they are fulfilling their educational role.

NPC's policies were deficient because they did not address speaker selection or performance issues for most of the Review Period. In the absence of policies, the Compliance Department deferred to Sales on these matters. With respect to speaker selection, sales associates were

---

79 *See* Gregory Schofield Deposition 115:5-15,116:7-25, 117:1-14; *see also* Leonard Brandt email, March 18, 2005, NPCLSV_LIY001384570, at 646-55 (Schofield Exh. 3) (physician spend not tracked or managed until 2005); *see also* NPC Supplemental Responses 3/10/2017, at p. 26 (honoraria caps implemented for certain speakers in 2005 to comply with state laws, and caps or thresholds for all speakers implemented in 2006); citing "Memo to Sales VPs", NPCLSV_LIT000501959 (regarding a speaker reaching their Honoraria Threshold for 2005); "Speaker Utilization Management, Managing Speaker Honoraria (email to the field) Revised Draft: 9/12/06", NPCLSV_LIT006367817 (noting that NPC established honorarium thresholds of $75,000 "a few months ago", which was being increased to $100,000 for local/regional speakers, $150,000 for national KOL speakers); "Speaker Utilization Policy Changes" Effective September 2006, NPCLSV_LIT006367969 at 7972 (KOL cap increased to $150,000, regional/local cap to $100,000).

80 *See, e.g.*, Mark Iwicki Deposition 283:17-284:17.

81 CV Speaker Utilization Update & Implications to Exforge, August 13, 2007, NPCLSV_LIT001392275.

82 *See* 2010 E&C Policies, § 6.11, p. 43 (NPCLSV_LIT000119375); 2009 PhRMA Code, at p. 10 (total amount paid to physicians in connection with speaking arrangement should be capped).

83 2002 PhRMA Code, at pp. 4-5; 2009 PhRMA Code, at pp. 7-10.

84 2002 PhRMA Code, at pp. 3-4.

85 2009 PhRMA Code § 6.

permitted to nominate HCPs to become speakers throughout the Review Period.[86] In my opinion, sales associates should have been taken out of the speaker selection process entirely, and HCP requests for speaking engagements should have been referred elsewhere in the organization. Instead, however, NPC put sales associates in the position of nominating, and in some cases, negotiating honorarium amounts with, HCPs who could refer or prescribe NPC products, an inherently risky situation.

This risk was exacerbated by a lack of clear guidance prohibiting sales representatives from considering the prescribing behavior of HCPs in making speaker nominations. The Compliance Policies did not address speaker selection until 2008, but even then provided minimal guidance, simply stating "[s]peakers should be selected based on their willingness and ability to deliver our approved promotional presentation to relevant audiences, but must in no way be selected as a reward for prescribing behavior or as an inducement for future prescriptions."[87] However, sales representatives were also told that it was "permissible to determine whether a speaker has prescribing experience, given the likelihood that those with clinical experience with our products will be the most effective promotional advocates in promotional speaking programs." [88] Without providing more specific instructions on how to distinguish between permissible and impermissible consideration of an HCP's NPC drug prescribing history, this provided cover for sales representatives to provide inducements to their customers in the guise of selecting "experienced" speakers. The best way to avoid this risk would have been for someone other than the sales associates to select speakers.

For most of the Review Period, NPC's Compliance Policies were also lacking because they failed to adequately describe how sales representatives should respond to speaker misconduct, such as failing to follow compliance rules, failing to present some or all of the program content, inviting spouses or guests, or sometimes even failing to show up (misconduct sometimes tacitly or explicitly approved by the hosting sales associate).[89] The NPC Compliance Policies did not provide rules for addressing speaker infractions until 2010.[90]

---

[86] Beth Margerison Deposition 98:12-22, 103:5-10; *see also* Natasha Nelson-Ling Deposition 217:8-219:3; Novartis Speaker Bureau Policies and Guidelines, July 20, 2003, NPCLSV_LIT006408894, at 901; Beth Margerison Deposition 210:19-214:13; Margerison e-mail to Alleta Aboulhoan *et al.*, June 21, 2005, re: Usable Speaker Process (Margerison Exh. 21).

[87] *See* October 2008 Ethics & Compliance Policies, NPCLSV00015272 at 312.

[88] Julie Kane e-mail to Anna Berardi *et al.*, July 20, 2007, NPCLSV_LIT000213958 ("Message from Legal and Ethics & Compliance Re: Speakers").

[89] *See* Audit of Sales Representative Interaction with Healthcare Professionals, June 23, 2009, NPCLSV_LIT001574780 (speakers made inappropriate comments, skipped or added slides, didn't disclose honoraria, but lead representative reported full speaker compliance); David Hollasch Deposition 261:15-265:3; Natasha Nelson-Ling Deposition 130:1-21, 139:6-140:12. Additionally, a speaker could also be paid for a cancelled event without having provided any services at all, raising an anti-kickback risk. The 2008

Continued on next page

III. The Compliance Departments and Officers

The OIG Guidance provides that an effective compliance program has a Compliance Officer and other appropriate bodies (typically a Compliance Department and Compliance Committee) with responsibility for developing, operating and monitoring the compliance program.[91] An effective compliance program begins with a formal commitment by the Board of Directors or other governing body, including the allocation of adequate resources, a timetable for implementation of compliance measures, and identification of a Compliance Officer responsible for ensuring that each of the recommended compliance elements is addressed.

Designating a Compliance Officer with appropriate authority is critical to a Compliance program's success. OIG Guidance recommends that the officer be a high-level official with direct access to senior management, the CEO, the Board and legal counsel, and that Compliance Department funding be a Board-level concern. These details are important because to be effective, the Compliance Officer must be able to exercise independent judgment and effectuate change within the organization.[92] The Compliance Officer's role and independence should be outlined in policies, and the Compliance Officer should have a regular schedule for appearing before the Board. A Compliance Officer is bound foremost by a duty to the organization and must be responsible and accountable.[93]

Continued from previous page

Policies implemented the first cancellation policy, providing that a Speaker Program should be cancelled if it was "greater than seven days away and it appears . . . there will not be the appropriate number of attendees." 2008 E&C Policies § 6.05; *see* David Hollasch email to Cindy Cetani and Natasha Nelson-Ling, June 4, 2009, NPCLSV_LIT001575464 (regarding lack of a policy communicated to field about payments to speakers for cancelled programs). NPC apparently did not adopt draft policy language on this issue that Compliance staff considered back in 2006. *See* "Straw man (DRAFT) policies regarding recently raised issues," NPCLSV_LIT000554785, at 786-87 (attachment to June 2006 Putenis email to Julie Kane, Cynthia Cetani, and others, NPCLSV_LIT000554784). A slide deck listing "Speaker Program Issues" for consideration at a July 28, 2009 Compliance Committee meeting stated that the "[c]urrent policy is 50% payment for NPC cancelled event 4-7 days prior, 100% 0-3 days prior" however, this "policy" did not appear in the Compliance Policies at the time. *See* "Compliance Committee July 28, 2009: Speaker Program Issues," NPCLSV_LIT000547199; David Hollasch Deposition 69:25-71:18 (discussing an analysis of "cancelled/paid" events and realizing there was no policy for when to pay speakers for cancelled events).

90 *See* 2010 E&C Policies § 7.04; 2011 E&C Policies, at p. 41.

91 OIG Guidance, at 23739-40.

92 *Id.* at 23739.

93 Health Care Compliance Association, "Code of Ethics for Health Care Compliance Professionals," accessed June 13, 2017, http://hcca-info.org/Portals/0/PDFs/Resources/HCCACodeOfEthics.pdf, § R2.4, p. 5.

The Compliance Officer and Department should operate under defined boundaries relative to the legal, internal audit, human resources, finance and security functions of the organization, allowing for the exchange of issues and solutions with these stakeholders. At the end of the day, however, compliance functions, policies and procedures should be established by the Compliance Officer and Department with approval of the Compliance Committee, senior management and the Board. This responsibility should not be delegated to business units.[94] The Compliance Department is responsible for drafting and implementing compliance policies, auditing and monitoring, education and training, enforcing standards and discipline, conducting risk assessments and making sure that the organization reports to regulators when regulatory violations occur. An effective compliance function should be able to spot-check problematic areas when necessary without first obtaining permission from the business owners of the risk.

Compliance programs suffer when compartmentalized, that is, when Compliance has its own silo, apart from other business units, finance and data collection. When compartmentalization occurs, individuals in each unit tend to view their job responsibilities in narrow terms and business units become comfortable with their limited view. The silos provide employees with plausible deniability, allowing them to comfortably say, "I was doing my job but did not know about a compliance breach [in another business unit]." Compartmentalization leads to rigidity about roles and directly interferes with compliance. An effective compliance program with an organized structure strongly supported by management helps business units understand that risk flows down through the entire operation and that every employee has a responsibility to ensure that future regulatory or law enforcement action does not become necessary.

The OIG also recommends that pharmaceutical manufacturers designate a corporate Compliance Committee to serve as a cross-functional resource with responsibility to spot compliance issues across the organization and bring them to the Compliance Officer's (and Board's) attention. The Compliance Officer and Compliance Committee have responsibility for developing, operating and monitoring the compliance program.[95]

Findings:

- **The compliance function at NPC lacked an effective structure and leadership until late 2010.**
- **NPC's Compliance Officers with oversight of Speaker Programs were overly deferential to the business, and were not effective at leading the Compliance Department with respect to Speaker Programs until late 2010.**

---

94 OIG Guidance, at 23739-40.

95 *Id.* at 23733, 23739-23740.

A. COMPLIANCE UNDER MARTINS R. PUTENIS AND (RUTH) ANN HARMON RAFFENSBERGER 2002-2005

Until 1999, NPC had no separate compliance function—compliance issues were managed by NPC's regulatory affairs and legal departments.[96] In 1999, Mr. Putenis, an 18-year veteran of NPC and its predecessor company with a marketing background, became Executive Director of Healthcare Compliance.[97] Mr. Putenis was responsible for establishing a compliance function that would "address various issues related to sales and marketing at Novartis," including Speaker Programs.[98] Healthcare Compliance was part of the Marketing Department until 2005 and during that time Mr. Putenis reported to Vice President of Marketing Operations Robert Doyle.[99] Mr. Putenis did not have a regular reporting relationship to the CEO or Board.[100] In fact, no NPC compliance employee had a direct reporting line to the CEO until July 2003 when Ruth Ann Harmon (also known as Ann Harmon or Ann Raffensperger) was appointed Vice President of the Ethics & Compliance Department, which was formed in 2003.[101]

Even after Ms. Harmon's appointment, major aspects of Speaker Program compliance, such as policies and training, were handled by Healthcare Compliance, which reported up to Marketing and not to Ms. Harmon.[102] This reporting structure continued until mid-2005 when Healthcare Compliance was merged into Ethics & Compliance.[103] Thus, there appeared to be no direct line of reporting to the CEO or Board about key aspects of compliance related to NPC's Speaker

---

96 Martins Putenis Deposition 24:20-25, 25:1-3.

97 *Id.* at 26:6-18, 27:24-30:24.

98 *Id.* at 26:13-18, 27:24-28:20, 139:8-142:2.

99 CEO/Executive Level Organization Charts, NPCLSV00018194.

100 *Id.*

101 NPC Supplemental Responses 3/10/2017, at pp. 11-12. Note: Novartis Corporation also had a compliance function. *See* e-mail between Elizabeth Henk and Ann Harmon, July 8, 2005, NPCLSV_LIT000019414, enclosing "Ethics & Compliance Report, 2Q 2005," June 2005, NPCLSV_LIT000019415. This compliance function apparently operated at a higher level than Healthcare Compliance at NPC. The materials under review did not contain reports prior to 2005 informing the Novartis Corporation Board about specific compliance issues concerning NPC's Speaker Programs. A Compliance report made to the Novartis Corporation Board of Directors in October 2003 by Novartis Corporation counsel was redacted in its entirety in the materials as privileged. *See* Status of Ethics and Law Compliance Program, Report to the Board of Directors of Novartis Corporation by Jeff Benjamin, October 30, 2003, NPCLSV_LIT006588883.

102 *See* Martins Putenis Deposition 26:13-18, 27:24-28:20, 139:8-142:2. Healthcare Compliance was described in December 2003 as a "unit . . . specifically focused on sales and marketing business practices and related policy and regulation." The OIG Compliance Guidance, December 5, 2003, NPCLSV_LIT006472355, at 441.

103 *See* Novartis Healthcare Compliance, "Compliance Connection" newsletter, February 2005, NPCLSV_LIT006289452, at 457.

Programs, which were a significant source of risk, until 2005.[104] This compliance reporting structure, in which Healthcare Compliance was buried several levels down within the Marketing Department, deprived NPC's compliance function of independence and made it less likely that Healthcare Compliance would act as an appropriate counterweight to Marketing's business goals.[105]

Additionally, NPC's division of the compliance function into two separate departments, Healthcare Compliance and Ethics & Compliance, from 2002 to 2005 prevented an effective, cross-functional review of Speaker Program risks and allowed compliance personnel to compartmentalize their responsibilities. Despite being a senior compliance officer at NPC with responsibilities for company-wide compliance standards, Mr. Putenis was uninformed about many aspects of the Speaker Programs.[106] His Healthcare Compliance Department had no responsibility for investigating violations of NPC policy or monitoring speaker events.[107] Furthermore, Mr. Putenis testified that if anyone at NPC was investigating or "auditing" speaker programs in the early years, it was likely Michael Shaw (who joined Ethics & Compliance in 2004) or someone in Internal Audit, but that the results of any such investigations were not communicated back to him.[108] Thus, Mr. Putenis did not receive information about Speaker Program violations that would have helped him draft more effective risk-based Speaker Program Compliance Policies. Similarly, Cynthia Cetani, who joined NPC in 2003 as an Associate Director in Healthcare Compliance, testified that she did not even know what the Ethics & Compliance Department did until after the merger of the two departments.[109] In my opinion, this compartmentalization was a basic structural flaw in NPC's compliance organization and may have been a root cause of many other failures.

Mr. Putenis, Ms. Harmon, and others with Speaker Program compliance duties also appeared to have no regular interaction with a proper Compliance Committee until 2005. NPC's Compliance structure from 2002 through 2005 apparently did not use an active, permanent, cross-functional

---

[104] *See* Novartis Pharmaceuticals Organizational Charts dated July 1, 2002 (NPCLSV0018198 to NPCLSV0018201), January 1, 2004 (NPCLSV0018211 to NPCLSV0018215), and July 1, 2005 (NPCLSV0018229 to NPCLSV0018233).

[105] The Compliance Departments needed authority and independence because the business frequently pushed back against limits that it tried to set. *See, e.g.*, Mark Iwicki Deposition, 251:21-252:9, 252:15-25, 253:7-254:7; Mark Iwicki e-mail to Thomas McCourt, Nov. 14, 2002, re: "PCOMT Follow Up PhRMA Code," NPCLSV_LIT001698047 (Iwicki Exh. 13).

[106] Martins Putenis Deposition 304:12-305:19 (no knowledge of results of investigations and corrective actions taken); 306:19-308:10 (little knowledge of results of audits).

[107] *Id.* at 38:15-42:4.

[108] *Id.* at 35:18-25, 38:15-39:10.

[109] Cynthia Cetani Deposition 20:25-22:1.

body to identify and effectively address compliance risks as described in the OIG Guidance.[110] This further isolated the Speaker Program compliance function.[111]

Other NPC compliance personnel testified that Mr. Putenis was not an effective compliance leader and on occasion, he actively resisted compliance measures designed to reduce Speaker Program risk.[112] Mr. Putenis testified at his deposition that he considered the business units responsible for compliance and that, in his view, training sales associates and monitoring Speaker Programs were the responsibility of sales management—that is, first-line managers, sales associates, and supporting departments such as Sales Operations.[113] Mr. Putenis' hands-off attitude towards compliance could not be effective, however, because the business units did not conscientiously or systematically audit their own Speaker Programs, *see infra* Part VI, and were motivated by sales goals that were in tension with compliance goals.[114]

Mr. Putenis appears to have ignored Speaker Program risks obvious to many others at NPC. For example, in March 2003, Joe McHale, Associate Director on the Diovan Marketing Team, wrote in an email that sales representatives were being allowed to "add speakers without any formal

---

110 OIG Guidance, at 23740, 23743, fn. 17 (emphasizing benefits of cross-functional compliance committee).

111 NPC had an "OIG Readiness Task Force" but it did not serve as a "Compliance Committee" as described in the OIG Guidance, *see* OIG Guidance, at 23740, because it did not act as an extension of the Compliance Officer to address known risks through corrective actions and policies. *See* OIG Taskforce Update and Novartis Consultant Network Recommendation, June 16, 2003, NPCLSV_LIT006800242, at 0245; Office of Ethics & Compliance Program Updates, August 18, 2004, NPC Compliance Network Meeting, NPCSV_LIT001358805, at 806 (referring to OIG Readiness Task Force). In my opinion, the OIG Readiness Task Force appeared to be mainly "window dressing" in the event of review by government regulators. Its main accomplishment appeared to be a collection of binders containing "compliance criteria" without correcting the ongoing Speaker Program risk. *See* OIG Readiness Task Force, Update Meeting-Final Phase, December 3, 2004, NPCLSV_LIT000203888.

112 David Hollasch Deposition 167:21-168:15, 308:12-310:9; *see also* Natasha Nelson-Ling Deposition 60:10-62:11, 169:3-171:7; Martins Putenis Annual Performance Review, 2004, NPCLSV_LIT012425768, at 774, ("One colleague noted, 'a strong commitment to Marketing, especially in the wake of dynamic regulatory and government issues.' However, one colleague expressed . . . sometimes you seem to try to satisfy marketing colleagues rather than take the tough but 'correct' stand."); *id.* at 775, ("a couple of colleagues felt you sometimes underplay the risks involved with certain issues . . . several others felt you had difficulty or were uncomfortable in taking on unpopular stands regarding major conceptual issues.").

113 Martins Putenis Deposition 40:25-42:4, 125:16-126:23, 143:7-147:16.

114 NPC's Codes of Conduct and Compliance Policies should have clearly defined the role of the Compliance Officer and Compliance Department, and emphasized their duty to develop compliance guidance, investigate misconduct, provide compliance training and conduct auditing of programs likely to cause risk. It was important for NPC to emphasize the authority and independence of the Compliance Department and this did not begin until 2010 after NPC began preparing for the CIA. 2010 E&C Policies, at NPCLSV_LIT000119421 (including new Chapter 15 on Ethics & Compliance Obligations).

training at all" which presented a compliance concern as "many reps will enroll top prescribers as speakers for obvious reasons."[115] This e-mail was forwarded to Beth Margerison and Susan Levinson, an executive in Marketing Operations who reported to the same supervisor as Mr. Putenis.[116] An effective compliance manager would have recognized the potential compliance risk where sales representatives were incentivized to increase sales by choosing high prescribers as speakers. Mr. Putenis testified that sales representatives were told not to use Speaker Programs as a reward for prescribing or induce physicians to prescribe, but did not acknowledge that using high prescribers as speakers presented a serious compliance risk, instead emphasizing the importance of permitting NPC to use speakers with "experience with the product" for effective marketing.[117] Mr. Putenis also took the position that if a sales representative and manager could "sleep well at night" then he was "okay" with a questioned practice.[118] It is my strong opinion that deferring to the judgment of the sales force was not an effective approach to compliance.

Mr. Putenis also facilitated questionable or risky Speaker Programs. For example, in February 2002, he approved a Speaker Program at a Memphis Grizzlies basketball game.[119] In March 2002, Mr. Putenis approved a Speaker Program at a fishing trip conducted off Chandelier Island on the Gulf Coast.[120] His justification for approving the fishing trip was that the compliance guidelines did not specifically prohibit this kind of event.[121] But it was Mr. Putenis who declined to draft more specific guidelines and relied on the sales force to use their own judgment to interpret ambiguous policies.[122]

Mr. Putenis' responsibilities remained largely the same after Healthcare Compliance was merged with Ethics & Compliance in 2005. He remained focused on policies throughout his tenure as Executive Director.[123] As discussed above, *see supra* Part II, the policies that Mr. Putenis drafted were not risk-based and contained numerous gaps.

---

115 Beth Margerison email to Susan Levinson, April 7, 2003, forwarding March 30, 2003 email from Joseph McHale, "Re: NEC Speakers," NPCLSV_LIT001494253 (Margerison Exh. 5).

116 *See* Novartis Pharmaceutical Organization chart, dated January 1, 2004 (NPCLSV0018211-15).

117 Martins Putenis Deposition 210:8-214:14.

118 *Id.* at 263:8-266:8 (discussing Putenis Exh. 12, NPCLSV_LIT006765422).

119 *Id.* at 257:12-259:8 (discussing Putenis Exh. 10, NPCLSV_LIT001133701).

120 *Id.* at 260:10-261:11 (discussing Putenis Exh. 11, NPCLSV_LIT001132738).

121 *Id.*

122 David Hollasch Deposition 134:2-15, 170:9-171:2, 172:6-173:18.

123 Martins Putenis Deposition 54:5-21.

There were few materials provided dealing with the role of (Ruth) Ann Harmon Raffensberger. The materials reflect that she worked in Ethics & Compliance in 2003, and served on the OIG Readiness Task Force.[124] An undated draft of "An Overview of NPC Compliance Program" lists her as the Vice President of Ethics & Compliance and NPC's Compliance Officer with responsibility for developing, operating and monitoring the compliance program, reporting directly to the President and CEO of NPC and the Board of Directors.[125] A search of materials revealed no indication that Ms. Raffensberger received regular reports about Speaker Program risk from Healthcare Compliance, or that she made regular reports about Speaker Programs, risks and corrective actions to the CEO, or the Board of Directors.

B. COMPLIANCE UNDER JULIE KANE, 2005-2010

Julie Kane became Vice President and Compliance Officer at NPC in late 2005.[126] Ms. Kane was not an effective Compliance Officer because she failed to comprehensively assess the risks posed by NPC's Speaker Programs and address those risks. Under Ms. Kane, NPC's policies continued to permit risky Speaker Programs and there was insufficient monitoring, auditing, and investigating of Speaker Programs even after internal and external reports suggested there was widespread non-compliance.

To begin, Ms. Kane did not identify the holes in NPC's Speaker Program Compliance Policies. Ms. Kane failed to recognize the risks imposed by repeat attendance.[127] She did not think it would be a violation of policy for the same HCP to attend the a Speaker Program on the same drug with the same attendees multiple times[128] and she was unsure whether NPC's policy prohibiting providing meals to HCPs more than "occasionally" even applied to Speaker Programs.[129] Ms. Kane testified that a Speaker Program in the middle of a restaurant might be appropriate[130] and she thought it possible for a physician to present a "fair and balanced" slide deck at a Speaker Program in a 10- or 15-minute time span if he or she was "really terrific."[131]

---

124 *See* OIG Taskforce Update and Novartis Consultant Network Recommendation, June 16, 2003, NPCLSV_LIT006800242, at 245.

125 NPC Compliance Program, NPCLSV_LIT003373745, at 745-46.

126 Julie Kane Deposition 27:4-28:10; NPC Organizational Charts, NPCLSV00018194, at 236.

127 Julie Kane Deposition 272:2-276:9, 279:4-283:2; *see also* Maria Woods e-mail to Julie Kane, January 15, 2008, re: "BPO Reports," NPCLSV_LIT006815186 (Kane Exh. 18) (risks of repetitive programs involving the same speakers and attendees coinciding with increase in speaker prescriptions).

128 Julie Kane Deposition 50:18-51:10, 272:12-279:3.

129 *Id.* at 96:19-99:19.

130 *Id.* at 89:9-23.

131 *Id.* at 58:2-24.

With respect to several Speaker Program risks that she did identify, she ultimately deferred to business interests at NPC. For example, Ms. Kane testified that she was concerned about the risks posed by sales associates' high targets for numbers of programs, but she did not assertively challenge those targets despite clear OIG Guidance about the risks.[132] Under Ms. Kane's supervision, Speaker Programs were approved at questionable venues such as casinos and resorts.[133] When the Compliance Department eliminated Ruth's Chris Steakhouse and Morton's Steakhouse as acceptable venues because they were "lavish," Ms. Kane agreed to reverse that decision on the business-centered grounds that it "might be easier to get doctors to attend if they can have the event at a well-respected and personally enjoyable restaurant."[134] Ms. Kane testified that in her view, what mattered was not whether the venue was appropriate, but whether the controls on Speaker Programs were "sufficient and adequate" to ensure events were conducted within the guidelines.[135] She believed that there were "better ways to manage the risk" than a blanket prohibition on high-end restaurants,[136] but she did not implement any.

Like Mr. Putenis, Ms. Kane emphasized it was primarily the business unit's responsibility to monitor its own activities without relying on Compliance.[137] Compliance apparently did not have access to the amounts the company paid to HCPs until the speaker utilization management program went into effect, around 2006.[138] Despite emphasizing the business unit's role in

---

132 *Id.* at 75:20-80:6; *see* OIG Guidance, at 23739.

133 *See, e.g.,* Marty Putenis email to Janet Wade, May 27, 2006, NPCLSV_LIT004575615 (Putenis Exh. 14) (approving use of a restaurant located in a casino); Marty Putenis email to Rick Chipman, August 28, 2006, NPCLSV_LIT006438306 (Putenis Exh. 15) (leaving it up to Sales to decide whether a "destination lodge" where "many physicians vacation" would be an "inappropriate luxury or extravagance"); *see also* Martins Putenis Deposition 276:3-281:7.

134 Julie Kane Deposition 215:17-216:17, 218:13-24, 219:11-220:4, 222:2-13 (discussing Kane Exh. 13, NPCLSV_LIT006588864).

135 *Id.* at 222:14-223:12.

136 *Id.* at 223:13-225:16. Contrary to Ms. Kane's testimony, 2006 controls were not sufficient to prevent "lavish" meals. NPC's 2007 Internal Audit revealed Speaker Program dinners frequently exceeded the $125 modest meal limit and such overages could detract from event objectives, generate cost inefficiencies and harm NPC's reputation. *See, e.g.,* Novartis Internal Audit, Operations Audit Report, "NPC Meetings and Events, August 6 to 24, 2007," Report No. 2007/46, NPCLSV_LIT000751260 at 264 (Kane Exh. 14). In 2007, Ms. Cetani advised Ms. Kane that 2,250 speaker events were "Level One" infractions meaning that they either exceeded $175 per person or the sales associate had three instances of exceeding $125 per attendee at a dinner program. *See also* Julie Kane Deposition 242:17-246:13.

137 Julie Kane Deposition 67:24-68:15, 69:6-9.

138 *Id.* at 134:10-21 (speaker utilization management was an effort to understand amounts being paid to speakers, unaware of any systematic monitoring of amounts paid to HCPs prior to February 2006); Kathy Bronshtein e-mail to Julie Kane, Feb. 8, 2006, re: "Speaker Honoraria Reports," NPCLSV_LIT000204817, with attached Speaker Utilization Management ("SUM") presentation, January 31, 2006, NPCLSV_LIT000204818 (explaining development of the SUM program) (Kane Exh. 7).

monitoring, the level of manager supervision over sales associates with respect to Speaker Programs decreased at one point under Ms. Kane's tenure. Sales Operations proposed that review of Speaker Programs be limited by removing the district manager's duty to sign off on pre-event approvals and post-event close-outs, a proposal Michael Shaw of Ethics & Compliance responded negatively to.[139] Ultimately, it appears the responsibility to report attendance and complete sign-in sheets was delegated to third party vendors. The report following the Q3 2008 Compliance Audit, *see infra* Part VI, concluded that this out-sourcing of review responsibilities contributed to Speaker Program violations.[140]

Under Ms. Kane, the Ethics & Compliance Department was undermined by its rigid structure. Compliance employees operated in separate silos: Ms. Cetani handled aggregate spend and state reporting,[141] Mr. Putenis handled policies and training, and Michael Shaw (and later Ms. Nelson-Ling) handled investigations (and later auditing and monitoring).[142] Although they communicated by e-mail, I observed that these individuals appeared to consider compliance issues outside of their "silo" to be someone else's problem and efforts to use a more interdisciplinary approach failed.[143] This compartmentalization hobbled Compliance's ability to effectively use tools at its disposal for key compliance purposes. For example, from 2005 until 2010 Ms. Cetani focused mainly on developing NPC's aggregate spend tool (which tracked the transfer of value or benefits to HCPs),[144] and was uninformed about the work of others in Ethics & Compliance.[145] It is not surprising then, that NPC did not use data collected by that tool for systematic monitoring until late in the Review Period, *see infra* Part VI.

My review also revealed a lack of attention to evidence of compliance violations under Ms. Kane. During Ms. Kane's tenure, the Compliance Department received Alertline complaints and other

---

139 *See* Michael Shaw e-mail to Beth Margerison, July 17, 2008, NPCLSV_LIT000554672 (rejecting the proposal to eliminate manager review/approval of events conducted by sales reps, as "[m]anagers play an integral role in identifying, monitoring, and addressing issues before they place the Company at significant risk"); *see also* "NEC-Based Proposals to Further Alleviate Manager Administrative Workload" (Version 5), July 17, 2006, NPCLSV_LIT000554675.

140 Audit of Sales Representative Interactions with Healthcare Professionals, June 23, 2009, NPCLSV_LIT001185049, at 059 (outsourcing responsibility for review of itemized meal receipts to AHM, whose employees were not physically present at Speaker Programs, was a poor control that caused excessive meal and alcohol costs).

141 Cynthia Cetani Deposition 19:22-20:16; Natasha Nelson-Ling Deposition 35:9-12, 35:25-37:18.

142 *See* NPC Organizational Charts, July 1, 2007, NPCLSV00018194; Cynthia Cetani Deposition 23:19-24:21; Martins Putenis Deposition 35:18-25; Natasha Nelson-Ling Deposition 35:1-37:18.

143 *See* David Hollasch Deposition 52:12-54:24, Nov. 29, 2016; Natasha Nelson-Ling Deposition 168:14-175:15, 186:25-187:12.

144 Cynthia Cetani Deposition 19:22-20:16.

145 *Id.* at 21:19:22:1, 23:19-24:21; *see also* Beth Margerison Deposition 98:23-99:16.

reports that sales representatives had committed serious violations of Speaker Program policies, falsified records of attendance, or permitted guests to order extra meals.[146] In 2007, Novartis Corporation's centralized investigatory body, the Business Practices Office ("BPO"), reported an increase in incidents of misconduct by NPC employees, including cases found to have merit involving "[m]isuse of events funds to influence healthcare professionals" and [p]ayments to healthcare professionals."[147] In December of 2007, Ms. Kane's counterpart at Sanofi-Aventis e-mailed her about the propriety of NPC's paying physicians $300-$600 to attend speaker meetings on Diovan in Buffalo, Rochester, Pittsburgh and Erie that year and about NPC inviting the "same seven doctors every month" to roundtables in Florida and paying at least two doctors a month to provide a talk or case study.[148] Similarly, twice in 2006, and again in 2008 and in 2009, posts on an online pharmaceutical industry message board and blog alleged that NPC's Speaker Programs were disguised vehicles for kickbacks to HCPs.[149] This should have caused a reasonably diligent compliance officer concern, and should have prompted action. Ms. Kane testified that she did not believe that the allegations in these posts were specific enough that Compliance could open an investigation.[150]

Internal reviews of NPC's events practices also demonstrated that there was widespread Speaker Program non-compliance while Ms. Kane was Compliance Officer. In April of 2006, Steven Chyung, Vice President, Strategic Sourcing-Americas at Novartis Corporation, sent Ms. Kane a draft report stating that 30% of Speaker Programs had fewer than three attendees and "modest

---

146 Mark Hennion e-mail to John Repsha, December 20, 2007, "re: BPO 550/2007," NPCLSV_LIT002616100.

147 Jeff Benjamin e-mail to Brian Reeve *et al.*, November 6, 2007, re: "2007 Annual Ethics & Compliance Report," NPCLSV_LIT007057674 (with attached presentations including "Business Practices Office, Statistics as of Oct. 25, 2007," NPCLSV_LIT007057676, at 678 ("NP4 cases have increased by 25%"), 683 (noting NP4 violations including "misuse of events funds to influence healthcare professionals" and "payments to healthcare professionals") (Kane Exh. 16); *see also* Julie Kane Deposition 248:12-254:4 (discussing Kane Exh, 16, NPCLSV_LIT007057674).

148 Mark Hennion e-mail to John Repsha and Julie Kane, December 20, 2007, "re: BPO 550/2007," NPCLSV_LIT002616100.

149 Michael Shaw email to Julie Kane, May 22, 2006, NPCLSV_LIT000202193 (Kane Exh. 11) (forwarding an email regarding the CafePharma posting alleging fake speaker programs and noting that they will "see if we can have this string pulled off the website"); Michael Shaw email, Feb. 23, 2006, re: "Electronic Cafepharma posting,", NPCLSV_LIT000203831 (forwarding an electronic version of the Cafepharma posting stating that "this is a way for Novartis to PAY its prescribers in hopes that they will compensate Novartis with scripts"); Dorothy Watson email to Julie Kane, Jan. 13, 2008, re: "Novartis reps claim speakers programs gone wild," NPCLSV_LIT003598725 (Kane Exh. 17); Natasha Nelson-Ling email to Michael Shaw, June 18, 2009, re: "CafePharma postings re: Novartis speaker program abuse," NPCLSV_LIT000215324.

150 Julie Kane Deposition 269:10-271:25.

meal" limitations were exceeded about 25% of the time (the "Chyung Report").[151] Mr. Chyung concluded Speaker Programs should be improved to increase effectiveness and reduce costs and provided a detailed plan for doing so.[152] A Dinner Meeting Excellence Task Force report from around the same time indicated a high-level of executive concern with "targeting key physicians" to improve return on investment for Speaker Programs and noted that while district managers had responsibility to enforce guidelines, they had no real incentive to monitor the activities of the sales force regarding dinner meetings.[153] And in September 2007, Ms. Kane received a report from Novartis Corporation Internal Audit that noted that meal costs and attendance numbers failed to comply with company policy, and recommended monitoring of Speaker Programs and increased accountability for accurate data reporting.[154] Speaker Program compliance risks could not have been more clearly spelled out for the Compliance Department and these reports' recommendations should have served as a road map for reform for Ms. Kane and her staff.[155] During the Q3 2008 Compliance Audit the following year, however, NPC encountered many of the same compliance issues, *see infra* Part VI.

In my opinion, Ms. Kane did not effectively respond to allegations of Speaker Program misconduct. An effective Compliance Officer uses information about reported compliance breaches to pinpoint risk, learn about system vulnerabilities or lack of controls and address compliance gaps. Ms. Kane did not respond to allegations of misconduct with a sense of the larger compliance issues indicated. NPC's materials reveal few instances of systematic, documented follow-up, or reports to the Board, CEO or other bodies to indicate that Ms. Kane was taking effective measures in response to reported risks. Compliance did not even begin

---

151 *See* April 20, 2006 email chain, NPCLSV_LIT000201827 (noting that "policies and controls around costs are not being enforced"; CEO Alex Gorsky comments "[t]he entire area of congress, events, speakers, and speaker management is complex and fraught with issues"), attaching "Congresses and Events Project Update, Draft Update," April 20, 2006, NPCLSV_LIT000201831 ("Chyung Report"), at 832 (noting that "cost controls and guidelines [were] not being followed" and "30% of meeting hav[e] less than 3 physicians per NVS associate"), p. 6 (over 25% of events exceeded the guidelines for average food & beverage cost per attendee); *see also* "Congresses and Event Project Update," April 12, 2006, NPCLSV_LIT000201668.

152 Chyung Report, at 845 ("Largest Identified Areas of Opportunity"); *see also* "Dinner Meeting Excellence Task Force Kick Off" presentation slide deck, June 12, 2006, NPCLSV_LIT001431565, at 567 (finding "3 major areas of opportunity to improve effectiveness and reduce cost in meetings and events").

153 "Dinner Meeting Excellence Task Force Kick Off" presentation slide deck, June 12, 2006, NPCLSV_LIT001431565, at 569 ("Objectives" include "[a]ssess how to target and attract the right people to improve ROI" and "End products" include "Strategy for targeting key physicians").

154 Novartis Internal Audit, "Operations Audit Report: Novartis Pharmaceuticals Corporation: Meetings and Events, August 6 to 24, 2007," Report No. 2007/046, September 10, 2007, NPCLSV_LIT001949230, at 232.

155 *See, e.g.,* Cynthia Cetani e-mail to Frank Unger, August 24, 2007, "Draft 5- Response provided for Ethics & Compliance 'in Charge' issues with Due Dates," NPCLSV_LIT000751258 (identifying issues in the Internal Audit for which Ethics & Compliance has responsibility, but also noting that for issues not listed, "[o]wnership of the other action items belongs with the business.").

auditing Speaker Programs until late 2008, *see infra* Part VI. In short, Ms. Kane did not exercise leadership qualities one would expect in a Compliance Officer dealing with evidence of serious, system-wide risks.

C. Compliance Under Cynthia Cetani, 2010-2011

In January 2010, Ms. Kane moved into a compliance role for Novartis Corporation and Ms. Cetani replaced her as NPC's Compliance Officer.[156] In her role, Ms. Cetani was responsible for the implementation of NPC's CIA and that was a large part of her job during the end of the Review Period.[157] Although NPC's compliance function was improved during that period, Ms. Cetani, like her predecessors, did not fully appreciate the risks NPC's Speaker Programs presented.

Ms. Cetani seems to have either misunderstood or underestimated Speaker Programs' AKS risks. In her deposition, she testified that she believed that for a Speaker Program to violate the AKS, there must be a *quid pro quo* (or "handshake") agreement between the speaker and the sales representative.[158] This narrow perspective allowed her to avoid in-depth review of HCP/sales relationships and failed to acknowledge the risk to an organization if it is unable to provide a legitimate business reason for a payment or benefit to an HCP (or if it violates the one-purpose rule). An effective Compliance Officer would not want sales associates to parse the AKS intent requirement this closely. Ms. Cetani also underestimated the risk presented by repeat attendance at NPC Speaker Programs.[159]

In sum, lack of effective compliance leadership with respect to Speaker Programs, a compartmentalized structure and deference to Sales and Marketing goals detracted from Compliance's effectiveness from the beginning of the Review Period until approximately 2010.

IV. Training and Education

OIG Guidance identifies the "training and education" of employees as an element of an effective compliance program.[160] A pharmaceutical manufacturer should communicate compliance standards through mandatory training programs.[161] Training materials should explain

---

156 Cynthia Cetani Deposition 25:8-16.

157 *Id.* at 296:9-298:19.

158 *Id.* at 39:1-23.

159 *Id.* at 33:9-37:3.

160 OIG Guidance, at 23731.

161 *Id.* at 23741.

compliance requirements in a practical, concrete manner.[162] All employees and contractors should receive general training about the compliance program, written standards, and applicable federal health care program requirements.[163] Employees and contractors whose job requirements make certain information relevant should receive more specific training; for instance, sales representatives should receive focused training on the AKS and how it applies to pharmaceutical sales and marketing practices.[164] Training should be tailored to make it as meaningful as possible for each group of participants.[165] Managers and employees of specific divisions can help identify specialized areas that require focused training.[166] Post-training review should be used to determine whether the training was effective.

Areas for training should be identified through internal audits and ongoing monitoring. An effective training program will cover both industry-wide compliance concerns and issues specific to the manufacturer. Each October, OIG publishes an annual Audit Work Plan identifying compliance targets, which can be used as a basic plan for annual training. The point is that training and education should be used to prevent and remediate risk. A pharmaceutical company should regularly update training to reflect issues identified through audits or monitoring, and changes in federal health care benefit requirements.[167] Compliance instructors should be qualified and sufficiently knowledgeable to coordinate discussions, and ideally available for follow-up questions.[168] New hires and contractors should be trained shortly after hiring and employees should be required to complete a minimum number of educational hours per year as a condition of continued employment.[169] The Compliance Officer should document formal training as part of the compliance program and keep training records including attendance logs, descriptions of the training and copies of training materials.[170]

The Compliance Officer is charged with developing and coordinating a compliance education and training program, as well as seeking to ensure that all employees and management comply

---

162 *Id.* at 23738-39 (training program for sales force should be "regular and comprehensive" including familiarizing sales force with minimum PhRMA code standards), 23740 (encouraging companies to "explain specific requirements in a practical manner").

163 *Id.* at 23740.

164 *Id.*

165 *Id.* at 23740.

166 *Id.*

167 *Id.*

168 *Id.*

169 *Id.*

170 *Id.*

with the pertinent federal and state standards.[171] Training materials should stem from clearly written policies and procedures so that employees understand the company's expectations. Employees should be fully informed about the company policies and any laws and regulations applicable to their jobs. The Compliance Department's duty to monitor and enforce compliance should also be explained and understood. Employees should be educated about management's duty to respond to violations and the corrective actions available to the company including disciplinary action, reporting and repayment. As a best practice, employees should fully understand the reasons behind their obligation to keep accurate records and report policy violations.

Findings:

- **Novartis's Speaker Program compliance training was poorly organized, contained mixed messages, did not fully or appropriately appreciate or explain Speaker Program risks related to illegal remuneration and was not informed by feedback.**

Throughout the Review Period, compliance training was fragmented between departments and there was no centralized coordination with various training systems. Mr. Putenis and his staff provided early compliance training primarily to managers with the expectation that training would "cascade" down to field-level sales representatives.[172] Kathy Bronstein, Director of Sales Operations, along with others working under her, provided Speaker Program training to sales representatives and managers, including how to enter event information into Novartis Event Central.[173] Prior to 2005, the Legal Department provided Code of Conduct and compliance training to newly-hired sales representatives and sales managers.[174] Compliance training was also provided by Sales Operations and Marketing with Compliance's participation when NPC "identified a need or an opportunity to train our people to make them more comfortable with the different policies and procedures."[175]

The NPC Compliance Department should have taken control of compliance training and maintained adequate documentation regarding the content, the audience, and whether training was effective.[176] For at least part of the Review Period, Compliance did not do so as indicated by

---

171 *Id.* at 23739.

172 Martins Putenis Deposition 28:4-10, 41:12-42:4, 44:7-14, 52:11-24, 64:2-13, 65:23-67:17.

173 Kathy Bronshtein Deposition 74:22-75:23, 109:21-24, 121:17-123:6, 123:23-124:7, 145:23-146:6, 228:3-230:2.

174 *See* NPC Supplemental Responses and Objections to Plaintiff's Notice of Deposition Under Fed. R. Civ. P. 30(b)(6), January 13, 2017, at p. 70; Kathy Bronshtein Deposition 33:21-38:5.

175 Martins Putenis Deposition 90:23-91:24, 149:22-151:3.

176 OIG Guidance, at 23740.

the results of a review of Healthcare Compliance Training conducted by the Internal Audit department in 2004. Internal Audit's report noted that NPC failed to comply with OIG requirements to train all relevant personnel in compliance issues because "[a]s of June 7, 2004, there were 302 field force associates that did not acknowledge understanding and commitment to the Healthcare Compliance guidelines within the given deadline of 60 days after hiring" and "associates that joined between October [2003] and March [2004] have not received" the promotional compliance online training that was implemented for new marketing staff.[177]

The content of NPC's compliance training materials was frequently confusing and contained mixed messages that emphasized optics over content, and often, sales objectives over compliance objectives. A review of a selection of NPC training presentation materials reveals that specific information about known Speaker Program compliance risks was not consistently conveyed to the sales force in simple, straight-forward terms. For example, the presentations should have clearly described the "one purpose" rule and explained the reason for the prohibition against allowing spouses or guests of HCPs to attend Speaker Programs and the risks inherent in repeat attendance. Instead, a sampling of the training materials reviewed sometimes addressed the "one purpose" rule and the no guests rule but, except once in passing, did not address the risks of repeat attendance.[178]

The presentations glossed over anti-kickback risks and had a "check the box" flavor, and even seemed to suggest that certain types of non-compliance might be condoned. For example, an October 2003 training presentation on how sales representatives should fill out call notes included a "Do Record" slide[179] and a "Do Not Discuss (*i.e.*, no call notes exist)" slide,[180] suggesting a distinction between having inappropriate discussions and recording such

---

[177] Novartis Audit, "Novartis Pharmaceuticals Corporation, USA, Operations Audit Report, Marketing Compliance, May 17 to June 11, 2004," June 21, 2004, Report No. 2004/35, NPCLSV_LIT006427694, ("2004 Audit Report"), at 7700.

[178] Of six Compliance slide decks sampled, only one stated that sales representatives "should not hold meetings on a reoccurring basis." November 2007, Ethics & Compliance Training (REF Meetings), NPCLSV_LIT000640613 at -640615. The remainder did not mention the AKS risks of repeat attendance at all. *See* Putenis Exh. 3, Healthcare Compliance Guidelines training, October 2003, NPCLSV_LIT000765536, (discussing no spouse rule but not "one purpose" rule); Cetani Exh. 3, NPCLSV_LIT000770037, The OIG Compliance Guidance, Nov./Dec. 2003, (discussing "one purpose" rule but not no-guest rule); Winning Ethically and Legally, Julie Kane and Dorothy Watson, Dec. 12-13, 2007, NPCLSV_LIT000733611, (no mention of spouse or guest prohibition and no mention of "one purpose rule"); Managing Speaker Issues, Oct. 12, 2009 NPCLSV_LIT0069254 (mentioning spouse prohibition but not "one purpose" rule); Overview of U.S. Enforcement, Compliance Environment, Conducting Business in the U.S., Cynthia Cetani presentation to Global Marketing, NPCLSV_LIT000753616 (mentioning "one purpose" rule and no-guest rule).

[179] Healthcare Compliance Guidelines training presentation, October 2003, NPCLSV_LIT000765536, at 569.

[180] *Id.* at 570.

inappropriate discussions in Call Notes if they did occur. At best, this training was confusing. At worst, the training suggested that sales representatives should conceal violations of the rules.

In December of 2007, NPC developed a compliance presentation for managers entitled "Winning Ethically and Legally."[181] It included several scenarios with hypothetical emails and lessons drawn from each. One example involved an employee who writes that he cannot find material responsive to a subpoena, and concludes "the best thing to do is not to tell Legal . . . So hush hush." The "lesson" for this scenario was "Obstruction of Justice" and "E-mail reflects ignorance of the import of written communications and puts Company at risk."[182] In the same presentation, one of the scenarios dealt with a physician who is awarded a clinical trial because of his status as the "number-one writer of" an NPC drug.[183] The "lesson" for this scenario was "Advocates Illegal Kickback" and "E-mail reflects ignorance of the import of written communications, and puts the Company at risk."[184] The training also emphasized "[i]f you don't have to write it, don't. Consider using the phone."[185] A June 2009 presentation for newly-hired sales associates used the same hypothetical email involving the selection of a doctor for a trial based on high prescription activity but replaced "Advocates illegal kickback" with "Activity illegal" and added a graphic containing the word "Duh!"[186] It is concerning that these training presentations repeatedly emphasized the risk of creating paper trails as the "lesson" across diverse scenarios. In my opinion, both presentations appeared to communicate more strongly that illegal activity at NPC should not be documented than that NPC sales representatives or managers should not commit illegal acts.[187]

---

[181] Winning Ethically and Legally, Ethics & Compliance training event presentation, December 12-13, 2007, NPCLSV_LIT000733611.

[182] *Id.* at 677-78.

[183] *Id.* at 679.

[184] *Id.* at 680.

[185] *Id.* at 686.

[186] Ethics & Compliance Presentation, Sales Representative New Hire Training, June 20, 2009, NPCLSV_LIT001267136, at 151-152.

[187] To provide a few additional examples of deficient training presentations, NPC presented a training entitled, "Good Compliance is Good Business: Compliance Awareness for New Hires" in February of 2007. (February 9, 2007, NPCLSV_LIT003328201). The presentation had attention-grabbing graphics and warned about scrutiny from law enforcement agencies. However, it contained no substantive discussion of specific compliance risks and did not address Compliance's role in protecting against fraud and abuse. In June 2007, Compliance developed training that explained changes in state law reporting, and referenced but did not explain in detail the AKS and Medicare Part D. It provided no information about the failure of Speaker Program cost controls or that a significant number of Speaker Programs had less than three attendees, were over modest meal limits, or had non-legitimate attendees. *See* Ethics & Compliance, Sales New Hire Training presentation slide deck, June 20, 2007, NPCLSV_LIT000210250, at pp. 26-42.

Finally, there appeared to be little pre- and post-training measurement of whether compliance training was effective or prevented policy violations during most of the Review Period. That is, NPC did not incorporate a training "feedback loop"—it did not use the results from monitoring and auditing to test whether compliance training messages "stuck" with employees, as demonstrated by the findings of the Q3 2008 Audit, *see infra* Part VI.

V. Effective Communication

The OIG Guidance identifies communication as another element of an effective compliance program. In my experience, effective compliance communication should flow freely both upstream and down: employees should be able seek independent compliance guidance from Compliance Department and Compliance should be able to receive information from the employees. Similarly, the Compliance Officer should be able to communicate upstream to the Board, CEO and Compliance Committee without resistance or hostility to the compliance message and receive direction.

The OIG Guidance breaks effective communication into two parts. The first is meaningful access to supervisors and/or the Compliance Officer through open-door policies between management and employees, and confidentiality and non-retaliation policies.[188] Compliance must be perceived as reliable and willing to act upon information received. The second part of effective communication is the use of hotlines, e-mails, newsletters, suggestion boxes, exit interviews, and other exchanges for communications.[189] Employees should be able to report matters on an anonymous basis and the Compliance Officer should maintain a log recording such reports and the results of any investigation conducted.[190]

Finding:

- **Novartis did not have effective lines of communication about Speaker Program Compliance until 2010.**

A. Compliance Communications Downstream to the Salesforce

Employees must feel free to ask questions and report problems for a compliance program to work. Supervisors usually play a key role in responding to employee concerns about compliance issues. But at NPC, managers' primary job was to promote sales, and like the sales associates, their compensation structure reflected that. Sales personnel needed access to a clearly identified,

---

188 OIG Guidance, at 23741.

189 *Id.*

190 *Id.*

independent compliance resource outside of their supervisory structure—someone whose compensation was not based on sales or business metrics.

While NPC had a non-retaliation policy, it was not widely believed by NPC employees.[191] Compliance Surveys at NPC from 2005 to 2010 reflected increasing distrust in management's non-retaliation promise. For example, in 2007, 45% of NPC employees said that if they witnessed a compliance violation, they would not report it "because they were afraid of retaliation"[192] compared to 34% in 2005 and 30% in 2006.[193] And 80% listed fear of retaliation as one of their top three reasons for not reporting a violation.[194] In 2009, 79% of all respondents "said that if they were to witness a violation they would not report it for fear of retaliation," and 47% of respondents who had witnessed a violation and had not reported it said they did so because they were afraid of retaliation.[195] These numbers were similar in 2010 (76% and 44%, respectively).[196] The 2011 Navigant Report noted that employee comfort levels about reporting incidents had further declined as of the 2010 Ethics & Compliance Survey.[197] "[C]ompany will not take action" was another leading reason stated for failure to report observed violations.[198] In the eyes of many of NPC's employees, Compliance was apparently not taken seriously.

---

191 In 2007, VP & Novartis General Counsel Jeff Benjamin reported on a Harvard Business School study designed to measure gaps between employees' perceptions about how the company should be performing and how the company actually performed. The average delta for U.S. companies was a .60 gap between "should be performing" and actual performance. When surveyed, employees of Novartis Corporation (comprised of all U.S. companies) reported a .96 gap with respect to non-retaliation. *See* Jeff Benjamin, Annual Ethics & Compliance Report to the Board, Novartis Corporation BOD Meeting, Nov. 6, 2007, NPCLSV_LIT007057690 at 691, 694. In his cover email circulating the survey results, Mr. Benjamin remarked that there was a "persisting issue of trust in the credibility and fairness of our managements." Jeff Benjamin email to Julie Kane, *et al.*, Nov. 6, 2007, NPCLSV_LIT007057674.

192 2007 Novartis Ethics Compliance Survey, Final Report: Novartis Pharmaceutical Corporation, February 6, 2008, NPCLSV_LIT003598583, at -599, 632.

193 2006 Novartis Ethics Compliance Survey, Final Report: Novartis Pharmaceutical Corporation, October 2006, NPCLSV_LIT001871484, 526.

194 2007 Novartis Ethics Compliance Survey, Final Report: Novartis Pharmaceutical Corporation, February 6, 2008, NPCLSV_LIT003598583, at 633; *see also* Julie Kane Deposition 283:7-285:22; Kane Exh. 19, NPCLSV_LIT035988470.

195 2009 Novartis Ethics Compliance Survey, Final Report: Novartis Pharmaceutical Corporation, August 11, 2009, NPCLSV_LIT006637453, at 467.

196 2010 Novartis Ethics Compliance Survey Results, December 22, 2010, NPCLSV_LIT000771537 at 573-74.

197 Navigant Report, at 886.

198 2006 Novartis Ethics Compliance Survey, Final Report: Novartis Pharmaceutical Corporation, October 2006, NPCLSV_LIT001871484, at 526.

When Ms. Kane became the Compliance Officer, she did not focus on making sure the field was receiving practical compliance-related communications. She testified in her deposition that policies were "somehow housed on the Internet" but she could not recall specifically how the policies were disseminated.[199] She also testified that Compliance spent time "ensuring" policies were brought to the attention of Sales and Marketing but was not sure how this happened.[200] A 2010 employee survey revealed that there was a 12% decrease from the previous year in the employee belief that NPC was "very successful in informing about commitment to code; messages [are] not resonating (91% via email)."[201] NPC's compliance messages was clearly not being effectively communicated at the time. The Compliance Department should have recognized that its communications efforts were not working, assessed the cause of this failure, and addressed it.

B. Communicating Compliance Issues Upstream To Senior Management

An effective compliance communication strategy also involves communicating upstream to the Compliance Committee, Board and CEO. Compliance Committees are useful communication tools that can gauge ongoing compliance risk. Risks discussed at Compliance Committee meetings can be incorporated into an audit plan or used to drive training. NPC apparently did not use a Compliance Committee for these purposes.

The materials reviewed demonstrated only sporadic Compliance presentations to the NPC or Novartis Boards prior to 2010.[202] Alex Gorsky, CEO of NPC from 2005 through February 2008, testified that he relied on Sales and Marketing (and input from Legal and Compliance) with respect to Speaker Programs.[203] Mr. Gorsky mistakenly believed NPC conducted "ongoing checks and audits" of the Speaker Programs.[204] However, this was not the case while he was

---

[199] In my opinion, it is significant that Ms. Kane had no recollection of how policies were disseminated to the field, Sales and Marketing. There appeared to be no routine process or system with respect to communication about the policies and any changes or revisions to them. On at least one occasion this generated confusion over an important compliance policy. In 2008 Ethics & Compliance promulgated a policy defining "legitimate attendee" that seems to have been communicated downward to the field in an ad hoc fashion, but even Compliance personnel remained unaware of the policy, and the definition was treated as "up in the air" for over a year. *See supra* Part II; David Hollasch email to Natasha Nelson, May 20, 2009, NPCLSV_LIT003270698; Natasha Nelson-Ling email to Eric Kizior, November 6, 2009, NPCLSV_LIT001479754.

[200] *See* Julie Kane Deposition 118:6-122:23.

[201] NPC Ethics & Compliance Report, NPC Board of Directors, March 9, 2011, NPCLSV_LIT000745844, at 849.

[202] *See, e.g.*, Board of Directors: Ethics & Compliance Update, June 21, 2007, NPCLSV00022651; Board of Directors: Ethics & Compliance Update, June 5, 2008, NPCLSV00022657.

[203] Alex Gorsky Deposition 10:13-19, 18:8-22, 27:3-15, 43:4-18.

[204] *Id.* at 67:6-25.

CEO, *see infra* Part VI. From this it appears that communication between Compliance and senior management during Mr. Gorsky's tenure was such that he was not fully informed of the risks run by NPC's promotional activities.

In March 2010, Ms. Kane advised the Novartis Corporation Board that Compliance would "consider adopting reporting by individual Company Compliance Officers at their respective US Company [Board of Directors] and/or Management Team Meetings."[205] This should have occurred years earlier as the NPC Board of Directors could better focus on NPC's compliance issues than the global parent Board.[206] Only as settlement loomed, did NPC's Compliance Officer (then Ms. Cetani) make semi-regular reports to the NPC Board as Compliance Officer as required by the CIA.[207]

VI. Monitoring and Auditing

The OIG Guidance identifies internal auditing and monitoring as part of an effective compliance program.[208] In healthcare compliance, "auditing" generally refers to an independent systematic examination to determine if a company's activities comply with laws, regulations and compliance standards, and the quantification of the results and calculation of an error rate.[209] "Monitoring" is systematic and continuous observation of an activity over time to determine whether ongoing practices are consistent with applicable laws, regulations and compliance standards.[210]

An effective compliance program uses both auditing and monitoring to measure its effectiveness. The Compliance Officer should develop a Compliance Program with benchmarks or measureable goals, set up a system to measure whether the program is meeting those goals, and if the goals are

---

[205] Ethics & Compliance Report, Novartis Corporation Board of Directors Meeting, March 11, 2010, NPCLSV_LIT001102058, at 059.

[206] *See generally* OIG Guidance, at 23739.

[207] *See* OIG-NPC Corporate Integrity Agreement, Sept. 28, 2010, NPCLSV_LIT001009931, at 935; *see also* Ethics & Compliance Report: NPC Board of Directors, September 22, 2010, NPCLSV_LIT000735534; Ethics & Compliance Report: NPC Board of Directors, November 8, 2010, NPCLSV_LIT000750311; NPC Ethics & Compliance Report: NPC Board of Directors, March 9, 2011, NPCLSV_LIT000745844.

[208] OIG Guidance, at 23731, 23741.

[209] The OIG and regulatory agencies, healthcare professionals and others involved with the healthcare and pharmaceutical industries commonly use the term "audit" interchangeably with "review," unlike a certified auditor in the accounting context, who would state that unless the review is conducted under professional audit standards, it is not an audit. See generally Public Company Accounting Oversight Board, accessed July 25, 2017, www.pcaobus.org/Standards/Auditing/Pages/AS1001.aspx (auditing) and www.pcaobus.org/Standards/QC/Pages/QC30.aspx; (monitoring).

[210] *See* Navigant Report, at 896.

not being met, determine why, and plan how to improve the program in the future.[211] An effective compliance program thus incorporates monitoring of its own processes as part of an ongoing evaluation of its effectiveness.

The OIG recognizes that the scope and frequency of compliance review (auditing or monitoring) may vary depending on the company's size, available resources, prior history of non-compliance and identification of risk factors.[212] As appropriate, a company may conduct a prospective systemic review of processes, protocols and practices, or a retrospective review of actual practices in an area.[213] Depending on the circumstances, review may include a "desk audit" where reviewers consider only documentation (and do no interviews), "data mining" where reviewers electronically comb through large amounts of data to find patterns indicating lack of controls or to identify the need for a more granular review, or a "field audit" where the reviewer is on site. The purpose of a compliance review is to allow the Compliance Department to gauge the effectiveness of the Compliance Program and to continuously improve it, reporting on progress to the Board and senior management.

The OIG provides that internal or external evaluators with relevant expertise should perform regular compliance reviews focusing on the departments of the pharmaceutical manufacturer with substantive involvement in federal health care benefits programs (such as Sales and Marketing). The reviews should specifically evaluate whether controls in place adequately manage risks. Specifically, reviews should evaluate whether (1) the pharmaceutical manufacturer has adequate policies to mitigate exposure in identified risk areas; (2) the policies were implemented and communicated; and (3) the policies were followed.[214] The Board should be informed of and feel comfortable with the audit plan and may also identify risk areas it seeks to evaluate (*e.g.*, effectiveness of training or executive compensation).

The Compliance Officer should identify the organization's risk areas. In my experience, this is typically done through a Compliance Risk Assessment,[215] *see supra* Part II, conducted by interviewing stakeholders involved in the risk area reviewed. The interviewees may be

---

211 *See generally* OIG Health Care Fraud Prevention and Enforcement Team, HEAT Provider Compliance Training slides, accessed July 25, 2017, https://oig.hhs.gov/compliance/provider-compliance-training/files/Provider-Compliance-Training-Presentationv2.pdf; Operating an Effective Compliance Program; https://oig.hhs.gov/compliance/provider-compliance-training/files/OperatinganEffectiveComplianceProgramFinalBR508.pdf, accessed August 3, 2017.

212 OIG Guidance, at 23741.

213 *Id.*

214 *Id.*

215 *See, e.g.*, Health Care Compliance Association, "We all assess risk – but what do we do with it?" by Deann M. Baker, accessed July 25, 2017, http://www.hcca-info.org/Resources/View/tabid/451/ArticleId/5157/We-all-assess-risk-but-what-do-we-do-with-it.aspx.

management, line employees or both. Compliance, or a contractor under its direction, will review documents relevant to the risk area as it conducts the interviews. The risks are then quantified; in some cases, this is done by a probe sample (non-statistically significant) followed by data analysis to determine the extent of the risk, including both its probability and the magnitude of the potential damage. If a probe sample shows a high error rate, Compliance should further investigate. Investigation may be conducted using a statistically significant sample that can then be used to extrapolate potential damages across a universe of claims or data. Whether any sampling is conducted, it is a common practice to document results of a Compliance Risk Assessment in a report) and to use a "heat map" (risk ranking) to document results showing areas of high risk, as defined by high potential damages, and/or high likelihood the risk will lead to damages.

Once the Compliance Risk Assessment has been completed, as a best practice, the Compliance Officer and staff should create a Compliance Audit Work Plan based upon the identified risks.[216] The Risk Assessment and Audit Work Plan are generally presented to and approved by the Board on an annual basis, but the Audit Work Plan should be a flexible document subject to modification as new risks are identified. Optimal auditing and review techniques are described in the OIG's Self-Disclosure Protocol and in CIAs published on the OIG's website. In its CIA processes, the OIG has found that Error Rates over 5% are unacceptable.[217]

Finding:

- **NPC failed to perform effective auditing and monitoring of Speaker Programs until late 2010 despite knowing these were events that presented high AKS and FCA risks.**

A. INADEQUATE COMPLIANCE RISK ASSESSMENTS AND WORK PLANS

In my opinion, NPC's Compliance Department did not conduct robust or well-organized Compliance Risk Assessments, as that term is understood in the industry, until after the CIA went into effect in 2010. The few "risk assessments" provided in the materials appear to be lists of high-risk areas without any supporting evidence explaining the basis for the assessment or

---

216 Cornelia M. Dorfschmid, "CIAs: Roadmap to a compliance officer's annual work plan?" *HCAA Compliance Today*, May 2016, pp. 33-36.

217 *See* OIG Office of Audit Services, "RAT-STATS 2010 User Guide," Version 1, accessed July 25, 2017, at http://oig.hhs.gov/organization/oas/ratstats/UserGuide2010_04js.pdf; *see also* OIG, "An Open Letter to Health Care Providers," Nov. 20, 2001, accessed July 25, 2017, at https://www.oig.hhs.gov/fraud/docs/openletters/openletter111901.htm (noting that a full statistically valid random sample will be required where the initial claims review identifies an "unacceptably high error rate," defined as over 5%, as set forth in the "Summary of New CIA Claims Review Procedures," accessed July 25, 2017, at https://www.oig.hhs.gov/fraud/docs/openletters/openlettersumm111901.pdf).

quantifying the likelihood of harm.[218] This is consistent with the testimony of Ms. Nelson-Ling and David Hollasch that in 2008, they worked from a "one-page" list of high risk areas that included Speaker Programs but that NPC did not have a "large formal risk assessment process."[219] Mr. Hollasch and Ms. Nelson-Ling used a short, unattributed risk list to determine priority areas for auditing and monitoring.[220]

The 2011 Navigant Report indicated that after the CIA, NPC conducted an annual risk evaluation largely driven by risks identified in the CIA.[221] This assessment involved sending a questionnaire to all business units and functional department heads seeking information about perceived risks, reflecting a more reliable methodology than previous efforts.[222] However, even at the end of the Review Period, NPC did not yet have a formalized risk assessment process in place. In September 2011, NPC drafted a Request for Proposal seeking "a Firm with significant, relevant experience to assist NPC's Ethics & Compliance [] Department in developing a formalized and structured risk assessment process."[223] This project was not yet completed by the end of the first reporting period of the CIA, as Navigant noted that "a more robust risk register and prioritization process was in development…including the risk ranking based on quantification of likelihood and impact of identified risks."[224] Ms. Cetani testified that when the Navigant Report came out (in December 2011), NPC was "building up the robust risk assessment" and Navigant "suggested that we further refine that monitoring from the risk assessment process, which is what we did."[225]

NPC's failure to take an organized approach to assessing and responding to compliance risk earlier contributed to the Compliance Department's lack of effectiveness during most of the Review Period. The Compliance Department did not conduct auditing or monitoring in an organized or systematic fashion. Instead, Speaker Program issues were discovered haphazardly and addressed on an ad-hoc basis with no effort to quantify or "heat map" particular risks. There was therefore no comprehensive, measurable plan to address them. Indeed, the materials show

---

218 *See* Ethics & Compliance Assessment of Risk Areas, Oct. 31, 2007, NPCLSV_LIT006906294; Draft Risk Assessments spreadsheet, NPCLSV_LIT007252205 (emailed in June 2010); *see also* 2010 Ethics & Compliance Risk Assessment, NPCLSV_LIT000944599.

219 Natasha Nelson-Ling Deposition 47:1-48:4; David Hollasch Deposition 138:14-140:9.

220 Natasha Nelson-Ling Deposition 46:10-21; David Hollasch Deposition 142:14-20.

221 Navigant Report, at 858.

222 Navigant Report, at 892.

223 *See* Ethics & Compliance Risk Assessment: Request for Proposal (RFP), Sept. 28, 2011, NPCLSV_LIT007208934, at 935.

224 Navigant Report, at 892.

225 Cynthia Cetani Deposition 304:20-305:10, 309:3-20.

that by mid-2008, NPC's Compliance Department had not yet formalized the processes necessary to perform an audit of field activity.[226]

NPC was slow to create an Audit Work Plan covering issues related to Speaker Programs. A work plan drafted in 2007 in response to the desk audit by NPC's Internal Audit department (discussed further below), appears to have been the first organized Compliance Audit Work Plan that addressed Speaker Program issues.[227] An effective compliance program would have included an *annual* Compliance Risk Assessment followed by an *annual* Audit Work Plan designed to address identified risks.[228] NPC did not do this.

B. Inadequate Monitoring and Auditing of Speaker Programs

1. Compliance Auditing and Monitoring from 2002 to 2007

NPC was aware that auditing and monitoring were important parts of an effective compliance program. A 2003 presentation about "Operationalizing the OIG Guidelines" included a recommendation that NPC "[i]mplement new guidelines regarding . . . Monitoring of Speakers and Speaker programs" and "[m]onitor utilization through regular reporting to identify unusual situations and trigger review and action."[229] Despite this knowledge, NPC was very slow to take action. Little was done to create any formal compliance auditing program until 2007 and no significant audit of Speaker Programs was performed by Compliance until the Q3 2008 Compliance Audit.[230] In the meantime, NPC relied on Novartis Corporation's company-wide

---

[226] *See* "Exhibit A, General Services Agreement, Task Order No. 5," NPCLSV_LIT001154254 (unsigned contract dated April 11, 2008 between NPC and consultant Potomac River Partners concerning Potomac's project to "[c]reate an audit guide to standardize the audit process"); *see also* Polaris Management Partners letter to Julie Kane, June 15, 2007, NPCLSV_LIT006767367, at 370 (draft proposal from vendor Polaris Management Partners discussing "Optional Workstreams," including an option to "[d]evelop NPC E&C Auditing charter" and to "[c]reate current risk assessment").

[227] *See* Cynthia Cetani e-mail to Frank Unger, August 24, 2007, re: "Draft 5 – Response provided for Ethics & Compliance 'In Charge' Issues with Due Dates," NPCLSV_LIT000751258 (attaching a copy of the draft Operations Audit Report for Meetings & Events (Aug. 6 to 24, 2007), Report No. 2007/046, NPCLSV_LIT000751260 (Cetani Exh. 7).)

[228] OIG Guidance, at 23741 ("regular compliance reviews"). In my experience, an annual Compliance Risk Assessment and annual Work Plan are best practices.

[229] Operationalizing the OIG Guidelines, July 28, 2003, NPCLSV_LIT006778114, at 140; *see also* OIG June 10 Meeting Notes, NPCLSV_LIT006448682 (emailed on June 12, 2003, NPCLSV_LIT006448681), at 682 ("Is the purpose of speakers to be able to pay them?"); *id.* at 688 (identifying risk areas including "Field force involvement," "Number of programs," and "Should we have speakers?").

[230] David Hollasch Deposition 49:25-50:13 (NPC auditing and monitoring function "in its infancy" when Hollasch joined company), 58:16-60:7; *see* Maria Woods Deposition 179:2-22.

Internal Audit function for (infrequent) auditing, with Compliance performing only occasional and limited spot checks with respect to Speaker Programs.[231] As to monitoring, NPC did not implement regular, systematic compliance monitoring of key Speaker Program risk areas until approximately 2010, and even then did not examine certain key risk areas at all. The ad hoc monitoring NPC did perform was insufficient given the evidence of significant, recurring non-compliance.

NPC's early auditing and monitoring efforts were minimal. At his deposition, Mr. Putenis stated that he had no recollection of any auditing or monitoring being performed by the Healthcare Compliance Department during the period he was its Executive Director.[232] According to Mr. Putenis, monitoring was not a "core responsibility" of Compliance but rather belonged to Sales Management.[233] Mr. Putenis testified that he realized around 2004 that monitoring was going to be an "important part of the compliance function" and required his staff become familiar with what he inaccurately labeled "monitoring" processes,[234] including going on "ride-alongs" or attending speaker events about four to six times a year.[235] Ms. Cetani also identified ride-alongs as a form of "monitoring" used by Compliance in 2003.[236]

In my opinion, these early observations were not "monitoring" as referenced in the OIG Guidance because they were not structured to gather information to help management or the Board with their responsibility to mitigate compliance risks through effective controls.[237] To be

---

231 For example, in January 2005, Polaris Management Partners ("Polaris"), a consultant, presented results from a 2004 review of Speaker Programs involving Dr. [redacted], who had received more than $225,000 as a speaker for 225 events. The results of the review indicated 34% of Dr. [redacted] reviewed programs deviated from NPC policy and involved host of data capture errors. In response, Polaris recommended, among other things, that NPC "[c]onduct regular compliance audits to confirm adherence to policies and processes," starting with "[d]evelop[ing] and establish[ing] core compliance audit competencies." Polaris Management Partners, Novartis Speaker Review: Final Presentation, January 21, 2005, NPCLSV_LIT000209388, at 433, 436. NPC did not begin developing those competencies for several years.

232 Martins Putenis Deposition 35:18-37:23, 40:25-42:4, 58:22-59:14, 59:19-60:12, 124:12-125:15, 125:20-126:23.

233 *Id.* at 38:15-42:4.

234 *Id.* at 35:18-37:9.

235 *Id.* at 41:5-19, 44:7-45:25, 54:22-57:12. Note: Healthcare Compliance generally announced it would attend a Speaker Program or ride-along before the event took place. *See* Cynthia Cetani Deposition 102:2-22.

236 Cynthia Cetani Deposition 96:10-97:19.

237 Ms. Cetani lumped many actions under the heading of "monitoring" that would be more accurately categorized as either training or reviews of expenses. *See id.* at 96:21-97:5, 102:23-103:3 (teleconferences to answer compliance questions), 108:9-23, 123:6-24 (discussions with sales reps if they raised questions regarding venues), 132:22-133:8 (conflating training with monitoring), 133:22-134:13 (field manager "coaching reports" as monitoring), 136:7-24, 139:13-140:13 (meals expense monitoring).

effective, auditing or monitoring should be followed by a report, which could then be used to develop a risk assessment or audit work plan, convey risks to senior management, or draft a corrective action plan to address unacceptable non-compliance. Neither Mr. Putenis nor his staff (which included Ms. Cetani during the years she reported to him, 2003 to 2006)[238] created any report of their observations during the ride-alongs or speaker events because, as Mr. Putenis stated in his deposition, "[w]e didn't have a process that required a specific report."[239]

NPC did not develop an auditing program for many years after the issuance of the OIG Guidance. In 2005, Ethics & Compliance Associate Director Maria Woods was charged with developing "the 'compliance auditing and monitoring element' of NPC's Commercial Compliance Program."[240] But by the end of 2006, Ms. Woods had "not deliver[ed] any results in this area" and apologized to her manager for this shortfall.[241] A 2006 chart comparing NPC's Compliance Program to each of the OIG Guidelines elements (and other benchmarks), described NPC's progress on the "[r]egular Auditing and Monitoring" element as "under development" and stated "[a]udit work plan needed."[242] Julie Kane's June 2007 presentation to the NPC Board of Directors included a slide entitled "Need to Enhance Compliance Audit, Oversight and Monitoring," which stated that "[i]n 2007, emphasis will be on: Formalizing auditing and monitoring program."[243]

NPC should have used the data that it collected about its Speaker Programs to monitor them for compliance violations. According to Ms. Cetani, NPC's launch of the aggregate spend tool Concerto (discussed further below) in 2007 was the beginning of its ability to monitor spending on Speaker Programs.[244] But in fact, NPC had already collected event data for years; it simply did not harness that data to effectively monitor for compliance violations until about 2010. Through the Novartis Event Central ("NEC") program, NPC had collected data for each speaker event since 2003, including the speaker's name, attendee names, program date, program location, honorarium amount, meal spend amount, presentation title, and relevant NPC drug.[245] Through a program called Report Central, NPC was able to generate reports using this data at least as early

---

238 NPC Organizational Charts, NPCLSV00018194.

239 Martins Putenis Deposition 57:4-12.

240 2005 Annual Performance Review for Maria Woods, NPCLSV_LIT012430879, at 885.

241 2006 Annual Performance Review for Maria Woods, NPCLSV_LIT012430894, at 898, 907.

242 NPC Compliance Program Comparison Tool, 2006, NPCLSV_LIT000205450, at 471-72.

243 Board of Directors: Ethics & Compliance Update, June 21, 2007, NPCLSV00022651, at 654.

244 Cynthia Cetani Deposition 122:2-9, 153:2-154:19 (discussing Cetani Exh. 4, Speaker Honoraria Management, NPCLSV_LIT000875959), 160:8-12, 162:2-21.

245 Beth Margerison Deposition 31:6-12, 33:8-34:9.

as 2004.[246] According to Polaris Management Partners ("Polaris"), one of NPC's vendors, Report Central could be used as a "[c]entralized reporting repository," for "[m]anagement reports," "[a]d-hoc functionality," "NEC Events – budget, projected spend, and actual spend data," as well as exporting and presenting data in multiple formats.[247] Indeed, the Chyung Report, whose purpose was to identify cost inefficiencies, utilized NPC's event data and found widespread non-compliance.[248]

For the most part, however, NPC failed to use collected speaker program data to monitor compliance with Speaker Program guidelines.[249] An example of a lost opportunity to use the data for compliance monitoring was an email chain from 2006 reporting that two enterprising district managers had discovered, using NEC data, that sales representatives had hosted multiple events on the same night with the same attendees.[250] This discovery was a one-off, and not the result of systematic compliance monitoring. In fact, the email chain noted that the managers would be informed of "the impropriety of their conducting such a thorough review absent compliance/security's awareness."[251] The only systematic compliance-related monitoring that seems that have taken place around this time was monitoring for speaker utilization and honoraria spending, to manage spending caps that were put in place in 2006 or early 2007, or limited monitoring for state law reporting purposes starting in about 2005.[252] While such

---

246 Proposed Report Central Landing Page, NPCLSV_LIT001285022 (2004 proposed webpage text concerning reports producible using Report Central); *see* Beth Margerison Deposition 40:9-23.

247 *See* Polaris Management Partners, "Promotional Programs" binder, Jan. 4, 2005, NPCLSV_LIT003315169, at 218.

248 *See* Chyung Report, *supra* Chapter III.

249 Beth Margerison Deposition 45:20-46:24 (does not recall Compliance having access to Event Central, Speaker Central, or Report Central, though Event Management Group, Marketing, and the field did have access); Natasha Nelson-Ling Deposition 201:11-202:20 (Compliance lacked either access or capability to pull attendance data and had to request it from AHM).

250 Maria Woods email to Ross Volk, June 27, 2006, re: "BPO Notification – Harris, Gray, Hogan, Barnette, and Cowan," NPCLSV_LIT001543332.

251 *Id.*

252 Cynthia Cetani Deposition 153:2-154:19; *see* Speaker Honoraria Management, March 22, 2005, NPCLSV_LIT000875959 (Cetani Exh. 4); NPC Supplemental Responses 3/10/2017, pp. 25-26; *see also* Aggregate Spend Planning Phase 2, Novartis Executive Committee, March, 22, 2006, NPCLSV_LIT006628848 at 851-57 (tracking aggregate spend, but not including speaker training costs or gift costs); Polaris Management Partners, Novartis Aggregate Spend Status Update, Nov. 18, 2005, NPCLSV_LIT003373918; Staying in Tune with Concerto, NPCLSV_LIT006649975, at 977 (discussing OIG guidelines for tracking HCP spend and the Concerto system); Gregory Schofield Deposition 115:5-24; Leonard Brandt e-mail to Alex Gorsky *et al.*, March 18, 2005, NPCLSV_LIT0001384570, attaching Speaker Honoraria Management document prepared by Cetani for March 22, 2005 meeting, NPCLSV_LIT001384646 (Schofield Exh. 3).

monitoring was better than nothing, it did not address many of the key AKS risk areas presented by Speaker Programs.

1. Reports by Novartis Internal Audit in 2004 and 2007

Before 2008, because NPC had not developed a compliance auditing function, it relied primarily on two reports by Novartis Corporation's Internal Audit Department—one report produced in 2004 and the other in 2007—for feedback about Speaker Programs' compliance with NPC's policies.[253] While these reports were limited in scope, they revealed that NPC's Speaker Programs frequently violated NPC's policies, that control gaps over Speaker Programs presented serious compliance risks, and that NPC needed to conduct much more robust auditing and monitoring.

The 2004 report summarized Internal Audit's review of certain "Marketing Compliance" aspects of NPC's business. The report "focused on the areas of promotional material, sponsorship and donations, congresses, as well as grants to institutions" and "tested on a limited basis compliance to the Code of Conduct."[254] As such, it provided little helpful information about Speaker Program compliance. The report did, however, report several serious issues with NPC's compliance training program,[255] *see supra* Part IV, conclude that NPC's "healthcare compliance guidelines do not include a clear definition of 'modest meals' [and a]s a result, excessive spending on meals may not be effectively prevented,"[256] and recommend that NPC develop an aggregate spend solution (prompting the development of Concerto).[257]

The 2007 Internal Audit report reviewed NPC's "Meetings & Events," including Roundtables and Speaker Programs (called "Dinner Meetings" in the report), "to assess internal control[s] regarding financial, operational, and compliance activities for effectiveness and efficiency."[258] The report also analyzed the Events Oversight Committee ("EOC") and speaker management

---

253 At her deposition, Ms. Cetani described Internal Audit as the third of three "lines of defense" against compliance violations. Cynthia Cetani Deposition 48:2-49:11.

254 Operations Audit Report Marketing Compliance, May 17 to June 11, 2004 ("2004 Internal Audit Report"), NPCLSV_LIT006427694 at 695.

255 *See id.* at 697, 702 (noting completion rates for code of conduct training as low as 70%, even "several months" after the given deadline, with "leadership associates" at only 59% completion rates).

256 *Id.* at 703.

257 *Id.* (recommendation to "[e]stablish a procedure to capture total spending" on HCPs and institutions).

258 Novartis Internal Audit, Operations Audit Report: Novartis Pharmaceuticals Corporation, USA, Meeting and Events, August 6 to 24, 2007, Report No. 2007/046 ("2007 Internal Audit Report"), NPCLSV_LIT001949230 at 231.

issues.[259] Internal Audit found that "[s]peaker events may not always comply with local company policies in regards to minimum number of participants and meal expense limits" and that NPC was unable to verify the accuracy of much of its event data, leaving the company blind to compliance failures that could impact Speaker Program effectiveness and cost, or result in reputational harm.[260] This message should have been NPC's wake-up call to better monitor event data accuracy, and conduct organized monitoring and auditing of the Speaker Programs.[261] Indeed, that was Internal Audit's explicit recommendation.[262] Management continued with its plans to outsource the planning and execution of events to vendor AHM rather than directly addressing the recommendation of better monitoring.[263]

Upon receipt of the 2007 Internal Audit findings, the Compliance Department should have taken responsibility for active oversight and monitoring of Speaker Programs. Instead of assigning oversight of remediation efforts to Ethics & Compliance (reorganized to be a unified department separate from Marketing two years earlier),[264] after the 2007 Audit, NPC again allocated responsibility for monitoring Speaker Programs to Marketing. And, Sales and Marketing management assigned to Sales Operations and Event Management the job of "ensur[ing] that speaker events are organized compliant to Novartis guidelines."[265] In my opinion, this was not an effective response to Internal Audit's observations and demonstrated Compliance's lack of institutional power and authority.[266]

---

259 *Id.* at 231; *see also* Cetani Exh. 7 (NPCLSV_LIT000751260); Cynthia Cetani Deposition 208:3-212:19.

260 2007 Internal Audit Report, at 232.

261 Cynthia Cetani Deposition 215:7-216:22.

262 2007 Internal Audit Report at 232 (recommended actions included "improved monitoring and analytical reviews" and "[e]nsure accountability for accurate reporting/data input by the field.")

263 *Id.* at 231 (outside vendor AHM was scheduled to take over events management in Q4 2007).

264 *See* NPC Organizational Charts, NPCLSV00018194 at 227 (Marketing Operations organizational chart as of Jan. 1, 2005), at 229 (CEO/Executive level organization chart as of July 1, 2005), at 231 (Ethics & Compliance organizational chart as of July 1, 2005).

265 2007 Internal Audit Report at 230, 232 (responsibilities assigned to Director of Event Management for General Meds, and Director of Sales Ops for Oncology).

266 The 2007 Internal Audit was confirmation that the pattern of non-compliance observed earlier had not changed. For example, a February 2005 presentation noted various forms of Speaker Program non-compliance, such as District Managers approving programs with fewer than three HCPs in attendance and "Speaker Certification Core Slide Deck . . . 1-2 slides used." OIG Task Force: HCP/O Spend Observations, Feb. 25, 2005, NPCLSV_LIT000083498 at 500-01. Commenting on this presentation, Marketing Director Susan Levinson wrote, "I think if we bring these issues up, we will get asked how often they are happening and what is the evidence. Not sure we are ready on all points to answer this." Task force member Kathy Bronshtein replied, "These things are happening. We don't need to investigate further. We need to make recommendations—establish policy and enforce this. The RLP [Dr. [redacted]] audit supports these

Continued on next page

2. The Q3 2008 and Nevada Audits

Ms. Nelson-Ling joined NPC as an Executive Director for Investigations, Auditing and Monitoring in May 2008 to set up a compliance auditing and monitoring program.[267] She included Speaker Programs as an audit area based on her experience working at other pharmaceutical companies and her attendance at various professional institutes.[268] The result was the NPC Compliance Department's first field audit of NPC's Speaker Programs, the "Q3 2008 Compliance Audit."[269]

Members of the audit team attended 45 Speaker Programs to assess compliance with NPC policies and the PhRMA Code, assess risk under various laws, and observe Speaker Program processes, financial controls, and controls on how Speaker Programs were managed. All audits were announced in advance; that is, compliance informed sales representatives and district managers that they would be auditing particular programs days in advance of those programs. Even so, the results of the Q3 Compliance 2008 field audit demonstrated that NPC had serious compliance issues.[270] Ms. Nelson-Ling observed that sales representatives and contractors running the meetings did not employ basic financial controls: representatives did not count heads or attendance for comparison to restaurant billing, did not have a copy of the PRC-approved slide decks on hand or communicate the need to adhere to approved materials, and selected tables in the middle of noisy restaurants in violation of NPC policy requiring a "room conducive to a medical discussion."[271] NPC compliance policies were frequently ignored at the Speaker Programs. In many cases, speakers did not cover the entire slide deck or were not professional in their demeanor. Of the 45 Speaker Programs in the audit, eight speakers were found to have

---

Continued from previous page

issues…. Can we get some traction on taking action!" See Kathy Bronshtein email to Cynthia Cetani, February 22, 2005, and prior email chain, NPCLSV_LIT000083496.

267 Natasha Nelson-Ling Deposition 34:21-25, 35:21-24, 44:10-17.

268 *Id.* at 48:14-49:1.

269 Audit of Sales Representative Interactions with Healthcare Professionals ("2008 Audit Report"), June 23 2009, NPCLSV_LIT001185049.

270 Natasha Nelson-Ling Deposition 104:9-107:8 (the Q3 2008 audit found internal process gaps for speaker programs related to locations, meal cost, audience, speakers, and reporting, and policies were insufficiently prescriptive), 108:7-110:10 (process gaps made it difficult to assess whether programs were violating AKS, but audit scope did not include investigating intent), 110:23-111:11 (audit showed issues with programs that they would have looked at more deeply if that was their purpose and they had the time).

271 *Id.* at 64:21-65:1 (sales reps sometimes interpreted "room conducive to a medical discussion" to permit a table in a busy restaurant); *see also* 2008 Audit Report, at 050, 058-60.

skipped slides[272] and many cardiovascular program speakers took less than 10-15 minutes in total to present the materials, raising the question of what the speaker was being paid for.[273]

The audited NPC Speaker Programs featured illegitimate attendees, excessive meal spending, and violations of the minimum attendance requirement. The audit team reviewed 36 field-led or AHM Speaker Programs, and nine programs conducted by an outside vendor called EXCEL. Three of the AHM programs had an insufficient number of HCP attendees (fewer than three HCPs) to qualify as a valid program. In twelve, or 33%, of the AHM programs, sales representatives reported an inaccurate number of attendees—the number of attendees was understated on nine programs and overstated on three.[274] As Ms. Nelson-Ling explained in the field audit results presentation, an "[u]nderstatement hides non-legitimate attendees (spouses or friends)" while an "[o]verstatement reduces the per person meal cost and can hide policy violations including [exceeding] the $125 meal limit per person and minimum three HCP attendee requirement."[275] In either case, an inaccurate count "result[s] in incorrect allocation of meal costs to HCPs."[276]

Seventeen of the AHM programs (47%) and 27 of the EXCEL programs (93%) failed to capture complete HCP information on the sign-in sheets and omitted data on the HCP's degree, specialty and/or address. Incomplete sign-in data may prevent proper allocation of meal spend or conceal inappropriate attendees. The audit team observed several attendees who did not appear to be "legitimate attendees."[277] Seven of the AHM programs (19%) were attended by non-HCP relatives of either the speaker or other HCPs,[278] suggesting that the programs had a strong social component and may not have been focused on education related to the NPC drug. Seven of the EXCEL programs had attendees whose specialties were in a non-cardiovascular arena, such as anesthesiologists, oncologists, pediatricians, and OB/GYNs, for whom the program was not appropriate education.[279]

The audit team noted sales representatives had no responsibility to review itemized receipts for accuracy of charges including excessive meals and alcohol ("wine decanted") and items charged as "to go." Eleven of the programs exceeded the $125 meal cost per attendee limit. Four of the

---

272 *See* Draft of 2008 Field Audit Results – Speaker Programs ("2008 Audit Presentation"), March 17, 2009, NPCLSV_LIT001591473, 476; *see also* 2008 Audit Report, at 057.

273 2008 Audit Presentation, at 476; *see* Natasha Nelson-Ling Deposition 129:13-133:1, 196:4-17.

274 2008 Audit Presentation, at 479.

275 *Id.*

276 *Id.*

277 *Id.*

278 *Id.* at 480.

279 *Id.*

programs' spend exceeded $185 per person. Twelve programs had excessive charges for alcohol of more than 20% of the pre-tax and gratuity total bill. The highest AHM program included charges of 27 bottles of wine for 31 attendees ($53 per attendee spent on wine). The highest EXCEL alcohol spend was 41 bottles of wine and 71 bar drinks for 56 attendees ($59 per attendee spent on alcohol).[280] Out of the 45 total programs examined, the audit found that NPC paid for a collective total of 42 additional, unattributed meals.[281]

The Q3 Compliance 2008 Audit also revealed various venue-related compliance violations including five programs (10%) that took place at venues where loud background music, noise and restaurant staff traffic continuously interrupted the speaker and medical discussion. Two (4%) of the events were held in venues where slides were visible to non-program participants and the discussion was not private. At two (4%) of the events, the slides were not presented on a large screen.[282]

The Q3 2008 Compliance Audit also demonstrated the data integrity issues described earlier. The audit report indicated that for 36% of the AHM speaker events, the number of attendees reported did not match the number on the sign-in sheet.[283] This was attributed to "representative failure to accurately record attendees."[284] The accuracy of Speaker Program data was crucial because it was a "critical driver" for compliance reporting of meal spend per HCP and monitoring for abuse.[285] Poor NPC data collection processes would significantly hinder use of programs such as Concerto as a compliance monitoring tool.

Overall, the Q3 2008 Compliance Audit team found that the internal controls over sales representative interactions with HCPs were unsatisfactory.[286] The March 17 Draft Audit Report noted there was no First Level Manager ("FLM") approval required for Speaker Programs because this requirement had been eliminated when speaker event outsourcing to AHM began.[287] NPC policies concerning sales representatives' responsibility for Speaker Program compliance were not clear. They gave representatives a false impression that they had no responsibility to count attendees physically present and compare them to those listed on the sign-in sheet; no duty to

---

280 *Id.* at 484. One wonders about the educational value of an event where 56 attendees consume 41 bottles of wine and 71 mixed drinks.

281 *Id.* at 485.

282 *Id.* at 487.

283 Draft of 2008 Field Audit Results – Speaker Programs, March 17 2009 ("2008 Audit Presentation (SPs Only)"), NPCLSV_LIT001355562, at 571.

284 *Id.*

285 2008 Audit Presentation, at 481.

286 2008 Audit Report, at 051.

287 2008 Audit Presentation (SPs Only), at 571.

ensure all attendees were HCPs of an appropriate specialty for the presentation; and no duty to confirm spouses and other relatives were not present (or were themselves legitimate attendees), or to submit correct attendance data.[288] The Draft Audit Report noted the outsourcing (and related confusion over sales representative responsibilities) caused many issues noted in the Q3 2008 Compliance Audit; these were control issues also revealed by the 2007 Internal Audit of Meetings & Events.[289]

The Audit Report noted that NPC was at risk of "fines and penalties for…providing gifts to physicians in the form of meals for non-HCP relatives attending programs [or for] holding sham speaker programs (insufficient attendees, venues not conducive to medical discussions),"[290] and recommended internal control improvements to address these issues. For example, the report recommended that management provide sales representatives with copies of slide decks to monitor speaker performance, sales representatives be clearly assigned the responsibility to evaluate speakers, and recommended systematic follow-ups by management to include periodic scrutiny of records for randomly selected events and routine examination of documentation underlying alerts on the FLM Dashboard Report that might be generated by anomalous or missing data.[291] The audit team provided tools to help sales representatives deal with attendance and performance issues. Ms. Nelson-Ling and her team recommended that FLMs review event records or checklists for compliance with policies[292] and that sales representatives be required to perform a head count, compare that number to the sign-in sheet, and resolve any differences noted. She recommended a reporting process with escalation up to the General Manager and BPO for those sales representatives who failed to complete sign-in sheets.[293] These are all reasonable, cost effective controls that should have been implemented earlier at NPC.

---

[288] *See generally* 2001 Guidelines; 2003 Guidelines; 2004 Guidelines; 2006 Guidelines; October 2008 E&C Policies; 2010 E&C Policies; Ethics & Compliance Policies, May 26, 2011, NPCLSV00014785; *see also* 2008 Audit Presentation (SPs Only), at 573.

[289] 2008 Audit Presentation (SPs Only), at 571; *see* 2007 Internal Audit Report.

[290] 2008 Audit Report, at 059 ("NPC may be subject to fines and penalties for . . . holding sham speaker programs").

[291] 2008 Audit Presentation, at 478; Audit Remediation September–October 2009, Kane Exh. 24, NPCLSV_LIT000451444, at 451-52, 471-81.

[292] Mr. Hollasch testified that business units were upset and resistant to recommendations requiring FLMs to assume more responsibility for Speaker Program controls and accurate data. *See* David Hollasch Deposition 319:9-24, 320:5-25, 322:9-19 (Hollasch had recommended FLMs review 100% of programs, but they were only required to review two per month), 324:3-326:23 (Internal Audit found that managers were just clicking "approved" on the Time & Expense (T&E) reports rather than actually reviewing these reports), 331:6-332:12 (repeated meetings were held discussing issues such as food-to-go, which should have been straightforward as it was against policy and against the PhRMA Code, but nothing was decided), 338:14-339:5 (some business unit heads were upset and angry following the 2008 audit).

[293] 2008 Audit Presentation (Nelson-Ling, Exh. 3), at 483.

Ms. Nelson-Ling presented the Q3 2008 Compliance Audit findings to Novartis CEO Ludwig Hantson and his direct reports.[294] Although Mr. Hantson wanted the internal control gaps "fixed overnight," Ms. Nelson-Ling testified the deeply entrenched bureaucracy at NPC made it difficult to rapidly change business practices.[295] Thus, while management agreed with the Q3 2008 Compliance Audit findings and recommendations, and signed off on a plan to implement remediation by October 1, 2009, a full year after the audit, remediation efforts had stalled.[296] After Ms. Cetani took over as Compliance Officer, NPC's auditing and monitoring budget was cut.[297]

Three of the 45 Speaker Programs that were attended as part of the Q3 2008 Compliance Audit were in Nevada and NPC's observation of those events (along with several ride-alongs) was used to comply with its obligation under Nevada state law to perform an annual audit of certain marketing practices.[298] Consistent with the overall Q3 2008 Compliance Audit results, the team found significant compliance issues with the Nevada Speaker Programs. Supporting documentation revealed excess food and beverages, including gifts to HCPs,[299] and several Speaker Program attendees who were identified as HCPs by sales representatives but whose HCP status could not be verified via Nevada Medical Board or Nevada Nursing Board websites.[300] There were six incidents where two sales representatives "split" costs when one representative paid for the drinks and another paid for the rest of the meal (doing so would keep the reported cost of meals under modest meal guidelines).[301] In my opinion, the internal controls on the sales representatives were clearly not effective, as Ms. Nelson-Ling recognized.[302] It appears, however,

---

294 Natasha Nelson-Ling Deposition 183:17-22.

295 *Id.* at 184:1-186:10, 186:10-187:12.

296 *Id.* at 226:5-20 (in mid-2009, Nelson-Ling was still "giving the same speech" and remediation was not moving forward).

297 *Id.* at 224:10-225:13 (budget for investigations and auditing was cut when Cetani took over for Kane); *see* E&C Audits and Investigations, Talking Points for Budget, 2010, NPCLSV_LIT000944577, at 579 (Nelson-Ling talking points for Audits and Investigations Budget Request for Q2-4, 2010, stating that "[c]urrent budget cuts reduced work/contractor hours by 4,151 from FY 2009" which is "[i]nsufficient resources to perform an adequate FF audit" and "[i]nsufficient investigator resources," emailed on March 23, 2010, NPCLSV_LIT000944575).

298 Draft Report "Nevada Audit for Compliance with NPC's Marketing Code of Conduct," July 17, 2009, NPCLSV_LIT001251028 (Kane Exh. 22).

299 *Id.* at 029, 031.

300 *Id.* at 029.

301 *Id.* at 032.

302 Mr. Hollasch's first draft of the report included a "satisfactory" opinion, which Ms. Nelson-Ling changed to "unsatisfactory." *See* David Hollasch Deposition 187:4-188:20, discussing Email from Hollasch to Nelson-Ling, July 28, 2009, Hollasch Exh. 7, NPCLSV_LIT001480228, attaching redline "Draft Report, Nevada Audit for Compliance with NPC's Marketing Code of Conduct" (showing "satisfactory" edited to

Continued on next page

that NPC certified to Nevada regulators that the internal controls over Nevada sales representatives were "satisfactory" anyway.[303]

3. Using Event Data for Compliance Monitoring

The materials and testimony reflect little-to-no organized compliance effort to monitor Speaker Programs until 2007.[304] Data on physician spend was tracked by Marketing and Event Management but was not easily accessible by Compliance.[305] This was a significant control gap preventing meaningful, ongoing review by Compliance of amounts spent on Speaker Programs.

NPC launched the Concerto aggregate spend review program in February of 2007.[306] The Concerto system combined information from about a dozen data systems (including NEC),[307] and depended upon accurate data entry by sales representatives, sales managers, third party vendors and Sales Operations.[308] Like NEC, Concerto identified the HCPs who served as speakers, when

---

Continued from previous page

"unsatisfactory"). Mr. Hollasch raised concerns with Ms. Nelson-Ling about implications of reporting unsatisfactory control to state regulators and the conclusion was changed back to "satisfactory." *See* NPCLSV_LIT006518974 (version dated July 31, 2009); NPCLSV_LIT001575495 (version dated Sept. 15, 2009); *see also* David Hollasch Deposition 327:21-328-8.

303 David Hollasch Deposition 180:2-18.

304 Natasha Nelson-Ling Deposition 95:6-97:14; Cynthia Cetani Deposition 136:7-137:6, 138:3-140:13.

305 Cynthia Cetani Deposition 122:2-123:5 (aggregate spend information began to be collected in 2007, but no one in compliance was using this data to track repeat attendance); *see also* Noah Puckowitz Deposition 216:7-219:5 (Puckowitz's team monitored honoraria caps in 2008 but did not start monitoring aggregate spend until 2015); Beth Margerison Deposition 141:24-143:14, 144:11-145:12 (Concerto had the ability to generate reports for speaker cap management but "nobody in compliance was responsible for the monitoring" of whether speakers were over their cap; this was the responsibility of the event management group).

306 Beth Margerison Deposition 40:24-41:11, 50:11-21 (the development of Concerto began in 2004 and it went fully live by February 2007); NPC Supplemental Responses 3/10/2017, p. 25 ("In February 2007, NPC began using Concerto"); Cynthia Cetani Deposition 122:2-9, 141:7-24, 158:5-159:18.

307 Cynthia Cetani Deposition 172:7-173:24; Concerto Fundamentals: A Guide to Understanding Concerto, NPCLSV_LIT003396884, at 889-91 (states ten systems exist currently to be fed into Concerto, and shows sixteen systems feeding into Concerto in a diagram).

308 In January 2007, Beth Margerison, Associate Director of Regulatory Compliance, worked on collection of Concerto data for speaker events and aggregate spend. In 2007, AHM took over managing speaker events and began collecting information about field-driven speaker events. Ms. Margerison used NPC applications as well as information from AHM and other vendors to feed data into Concerto. *See* Cynthia Cetani Deposition 169:6-175:23, 183:11-184:2, 185:7-17, 192:7-21; *see also* Cynthia Cetani email to Michael Shaw, April 3, 2007, Cetani Exh. 5, NPCLSV_LIT000921882 (noticing inaccurate data found during testing of Concerto).

they spoke and how much each speaker received in honorarium, as well as the names of attendees and total meal spend amounts.[309] Concerto became fully operational in 2007[310] and was used primarily to collect information for state law reporting purposes (and later the federal Physician Payment Sunshine Law), but also to track physician spend and calculate how much had been paid to a physician with respect to annual honoraria caps.[311]

The Concerto data was often inaccurate[312] due to the failure by sales representatives, vendors and managers to submit timely and accurate reports. Ms. Cetani testified that inaccurate or incomplete data limited her ability to monitor whether Compliance Policies were being followed, but also that she believed the Concerto data was sufficiently reliable to calculate meal spend.[313] The Compliance Department used Concerto data in its reports to various states[314] because necessary reporting information was otherwise unavailable. Ms. Cetani testified about Compliance making efforts to correct data coming into Concerto.[315] According to Ms. Margerison, ensuring data accuracy was not the Compliance Department's duty but was the responsibility of individuals inputting the data.[316] An effective compliance program would have continuously tested the Concerto data collection tool to quantify the reliability of underlying data, refine data collection processes, and improve Concerto's accuracy.

Notwithstanding these accuracy issues, Concerto was under-utilized. The data Concerto collected could have been used to systematically monitor for illegitimate attendees, repeat attendance, modest meal violations, insufficient attendance and other types of Speaker Program non-compliance. Yet even after it developed Concerto, NPC did not routinely use the data for

---

309 *See* Cynthia Cetani Deposition 176:6-13 (Concerto allowed tracking of honoraria), 180:4-20, 181:18-182:18, 229:17-20 (Concerto used to track meal spend and venues), 267:22-269:3 (Concerto could be used to match attendee names to databases of HCPs to detect fake names); Beth Margerison Deposition 141:24-142:13 (Concerto could track speaker caps); 2007 Internal Audit Report, at 232, 235.

310 NPC Supplemental Responses 3/10/2017, p. 25.

311 Beth Margerison Deposition 43:8-44:16.

312 David Hollasch Deposition 296:20-300:17 (discussing April 7, 2011 email, NPCLSV_LIT003383021 (Hollasch Exh. 14)).

313 *See* Cynthia Cetani Deposition 169:13-171:24, 172:7-175:23 (Concerto data was sufficiently reliable to calculate meal spend "understanding that there were going to be some anomalies that we would have to go back and address and correct"); Noah Puckowitz Deposition 214:8-10 ("[W]e've at times found discrepancies in data. But generally speaking, the data was good in Report Central.").

314 Cynthia Cetani Deposition 232:11-20; Mark Tramposch Deposition 52:11-53:21 (Concerto data was used to produce reports to comply with state laws as well as to potentially meet Sunshine reporting requirements).

315 Cynthia Cetani Deposition 170:9-171:24, 173:18-175:23.

316 Beth Margerison Deposition 165:21-168:14.

compliance monitoring purposes until near the end of the Review Period.[317] Maria Woods testified NPC was "implementing a compliance field-based monitoring program as I was leaving the organization [in 2008]. Other than that, there would have been monitoring happening from the sales perspective, from sales monitoring."[318] Ms. Cetani testified that it was possible to discover violations of the modest meal policy using Concerto data analysis but this was not done right away "because we had to look at getting accurate tracking for the purpose of aggregate spend reporting."[319]

An example of how Compliance could have more effectively leveraged Concerto would be through mining event data to determine the number of times a physician attended the same Speaker Program on the same drug.[320] Ms. Nelson-Ling testified that she did not include repeat attendance at Speaker Program meetings in her pre-audit compliance risk checklist in 2008 because she did not know how to pull this information.[321] Ms. Cetani had access to this information because she managed Concerto and could have provided repeat attendance data to Ms. Nelson-Ling for auditing purposes.[322] But neither Ms. Cetani nor Ms. Kane considered repeat attendance to be a serious compliance risk.[323]

Instead, NPC produced occasional "exception reports" listing all instances of a specific type of non-compliant program during a particular time frame. For example, in October 2007, Ms. Cetani reported to Compliance Officer Julie Kane the discovery of 2,250 Speaker Programs with spending in excess of $175 per person or multiple violations of "modest meal" policy by a sales representative.[324] However, "exception reporting" was not a regular process assigned to the Compliance Department.[325] Sometime in 2009 or 2010, NPC added a modest meal monitoring function to the "FLM dashboard," used by sales managers.[326] As of September 2010, Compliance's

---

317 At first, Concerto only used to track honoraria and establish spending caps processes. *See* Cynthia Cetani Deposition 175:24-176:19.

318 Maria Woods Deposition 109:18-110:2.

319 Cynthia Cetani Deposition 179:16-185:6, 188:18-189:2.

320 *See, e.g.*, David Hollasch Deposition 105:3-106:7 (one sales representative submitted expenses for sales call meals with the same physician 22 times in a single month).

321 Natasha Nelson-Ling Deposition 196:18-198:14, 201:3-202:20, 262:8-18.

322 *Id.* at 198:15-199:2.

323 Cynthia Cetani Deposition 33:9-36:1; Julie Kane Deposition 50:18-53:17, 55:19-25.

324 Julie Kane Deposition 242:17-243:6 (discussing Kane Exh. 15, NPCLSV_LIT000945907).

325 Beth Margerison Deposition 92:17-95:11, 141:24-143:11; Cynthia Cetani Deposition 230:22-233:7.

326 Beth Margerison Deposition 90:5-92:8.

modest meal monitoring program was in development but had not yet been implemented in its final form.[327] Monitoring of legitimate attendees did not begin until 2012.[328]

In my opinion, Compliance should have used Concerto and its predecessor systems to data-mine much earlier in the Review Period, and should have used it more broadly. Concerto was a built-in monitoring tool.[329] It could track gift payments to HCPs, honoraria and all events over a certain monetary threshold. It could capture and "flag" problematic venues such as casinos or spas. Concerto could track attendees and calculate meal spend. It could calculate the number of meals over $125 per HCP.[330] These metrics should have been used to identify and target problematic geographic regions (or individual managers and sales representatives), conduct strategic Speaker Program compliance training, adjust incentive structures, and evaluate whether such measures improved compliance. Compliance apparently resisted using Concerto in this manner.[331] Considering the other red flags of Speaker Program abuse from 2007 onward, Compliance's limited use of Concerto was short-sighted.

4. Navigant's 2011 Review as Compliance Expert

Although Novartis's auditing and monitoring program had improved by 2011, it still had serious flaws even after reforms were made in the wake of the settlement and CIA. In its Compliance Expert Report, Navigant noted that by 2011, audits and corrective actions were well-documented and reported,[332] but the Compliance Program had only "partially" incorporated monitoring. Monitoring remained "largely the responsibility of the business," whose responsibility to report results to the NPC Compliance Committee was "less well defined."[333] Documentation of audits and ongoing monitoring, including reports of suspected noncompliance, were only "partially"

---

327 Cynthia Cetani Deposition 284:4-285:24.

328 *Id.* at 324:4-23.

329 The materials include references to NPC's expectation that vendor AHM would perform compliance functions. For example, the Q3 2008 Compliance Audit Report states that "Upon inquiry with AHM, we noted 791 representatives indicated from 1/1/08 to 3/11/09 that speakers had violated NPC Policy. These policy violations were not being followed-up on." 2008 Audit Presentation, at 474. In addition, there was a plan for AHM to perform some exception reporting beginning in 2011. *See* Mark Tramposch Deposition 108-10 (discussing NPCLSV_LIT003383021, Tramposch Exh. 11); Gregory Schofield Deposition 76:12-25 (use of AHM and Genesis to monitor who speakers were and how much they were paid).

330 Cynthia Cetani Deposition 228:25-229:12 (gift tracking), 230:13-21 (tracking specialties of event attendees), 233:8—234:15 (venues), 234:25-235:23 (number of attendees).

331 *Id.* at 230:2-235:23, 236:2-15, 247:21-250:8.

332 Navigant Report, at 858.

333 *Id.*

provided to senior management and the Compliance Committee.[334] NPC still had work to do to determine whether the Compliance Program was working, and whether ongoing monitoring was effective.

Navigant specifically found the Compliance Risk Assessment process would be enhanced by internal consideration of written policy updates, a feedback loop from previous audits, monitoring and the Alertline, and feedback from investigative processes. Navigant recommended a risk ranking (heat map) incorporating the potential impact of certain risks and the level of risk control quantification to support the ranking.[335] Navigant recommended that written standards be developed to provide guidance on risk assessment, auditing and monitoring. Most importantly, Navigant recommended that written standards provide a consistent approach to reporting and follow-up.[336]

Navigant noted organizational confusion over compliance auditing and compliance monitoring that made assignment of responsibilities for these tasks unclear. Navigant recommended incorporating well-known definitions for these terms into NPC's written standards and recommended that Compliance conduct compliance auditing and monitoring as a follow-up to audit results. Reporting of monitoring results was to be incorporated into the annual work plan, including the nature of the monitoring, who was responsible for it, and how reports were to be generated for the Compliance audit team, the Compliance Committee and the Board.[337] Navigant also recommended field managers be trained to use the Field Coaching Report to document compliance violations and establish accountability at the field level.[338]

VII. Investigations and Discipline

OIG Guidance makes clear that the Compliance Officer is responsible for "[i]ndependently investigating and acting on matters related to compliance" and "should have the flexibility to design and coordinate internal investigations (*e.g.*, responding to reports of problems or suspected violations) and any resulting corrective action (*e.g.*, making necessary improvements to policies and practices, and taking appropriate disciplinary action) with various company division or departments."[339] Properly conducted internal investigations should lead to immediate remediation and, in my opinion, should be conducted whenever the Compliance Officer has a

---

334 *Id.* at 894.

335 *Id.* at 895.

336 *Id.* at 896.

337 *Id.* at 896.

338 *Id.* at 897.

339 OIG Guidance, at 23740.

"reasonable suspicion" to believe there is a violation of the Compliance Policies, law and/or regulations.[340]

OIG Guidance provides that an effective compliance program should include clear and specific disciplinary policies explaining the consequences for violating the law or written standards.[341] Intentional non-compliance should reliably subject transgressors to sanctions ranging from verbal warnings to additional training, compensation clawbacks, suspension, termination or other measures. Discipline may be appropriate where an employee's failure to detect a violation is attributable to negligence or reckless conduct. For discipline to have a deterrent effect, a pharmaceutical manufacturer must undertake appropriate, consistent disciplinary action across the company.[342]

Findings:

- **NPC did not have a program for the systematic and effective investigation of Speaker Program misconduct until 2010. Investigations of individuals were too infrequent and often delayed, creating little deterrence for sales representatives tempted by Novartis' financial incentives to misuse Speaker Program funds, and Novartis failed to investigate obvious program-wide issues.**

- **NPC did not enforce Speaker Program compliance through consistent and appropriate discipline.**

A. INVESTIGATIONS OF COMPLIANCE VIOLATIONS

NPC did not have an effective compliance investigation function until 2010. Before 2010, compliance investigations were conducted too infrequently to be effective, and the investigations that were conducted were protracted, taking too long to complete or left unresolved. As a result, NPC was unable to confirm many instances of non-compliance and appropriately discipline the

340 *Id.* at 23742.

341 *Id.* at 23741-2.

342 *See* 2011 Federal Sentencing Guidelines Manual, p. 515, Commentary to § 8B2.1, Effective Compliance and Ethics Program ("Recurrence of similar misconduct creates doubt regarding whether the organization took reasonable steps to meet the requirements of this guideline"), accessed August 10, 2017 at https://www.ussc.gov/sites/default/files/pdf/guidelines-manual/2011/manual-pdf/2011_Guidelines_Manual_Full.pdf; Remediation, Litigation Services Handbook: the Role of the Financial Expert, Jonny Frank, 5th Ed., Chapter 13A.2, p. 4 (emphasizing the importance of timely and effective remediation upon investigation of business misconduct), accessed August 10, 2017 at http://stoneturn.com/wp-content/uploads/2016/02/Remediation_Litigation_Services_Handbook.pdf.

individuals involved. By failing to discipline individuals for Speaker Program non-compliance, NPC did not adequately deter others from engaging in Speaker Program-related misconduct.

My review did not uncover a formal structure in place for investigating Speaker Program compliance violations at NPC until about 2005.[343] Michael Shaw, Ethics & Compliance Director of Investigations, created a process for conducting internal investigations of compliance issues that was finalized in late 2004 or early 2005.[344] When the investigation of a particular case was complete, the case was sent to the Resolution Committee ("RC") for a recommendation as to what discipline (if any) was warranted.[345] An NPC internal document characterizes the investigations process before Novartis created the Business Practices Office ("BPO") in mid-2005 to centralize the handling of allegations of misconduct across all of its subsidiaries' operations worldwide,[346] as "chaos and confusion."[347] According to this document, there was "[n]o overall process owner for misconduct & fraud prevention, detection and reporting," "[n]o clear policies, roles and responsibilities," "[n]o common understanding of what constitutes misconduct," "[i]nsufficient encouragement and protection of whistleblowers," "[d]uplication/potential gaps in misconduct reporting to management," "[n]o consistent assessment of misconduct/fraud risks," "[i]nconsistent remediation of misconduct cases," and "[i]nsufficient attention to learning lessons from actual misconduct cases."[348]

Even after Novartis created the BPO, however, its investigations process lacked coordination. In 2011, Navigant found that the "investigations process is not standardized and there are no policies or procedures that specifically address the process of conducting an investigation . . . [or of] reporting investigation results to the RC," which "could make it more difficult for the RC to apply a consistent standard across multiple cases."[349]

---

343 *See* Julie Kane Deposition 26:9-16; *see also* Office of Ethics and Compliance Program Updates, Aug. 18, 2004, NPCLSV_LIT003297464, at 477 (presentation listing as an initiative "Protocol for NPC Internal Investigations," and as "Objectives" "formaliz[ing] current practices and element[s] of compliance program" and "enabl[ing] accurate internal reporting of active/past investigations"); Polaris Management Partners, Compliance Program binder, 2004, NPCLSV_LIT003314868, at 911-12.

344 Maria Woods Deposition 22:14-20, 44:2-46:21 (discussing Woods Exh. 1, NPCLSV_LIT000814717).

345 Cynthia Cetani Deposition 187:18-188:5.

346 *See* Julie Kane e-mail to Michael Shaw, November 4, 2005, NPCLSV_LIT000941685 (Novartis Corporation BPO established by Novartis Board of Directors on November 2, 2005); *see also* Guideline for Handling Reports of Possible Misconduct, Effective Nov. 2, 2005, NPCLSV_LIT000941687; Julie Kane Deposition 35:22-36:1 (BPO centralized investigations of misconduct across subsidiaries).

347 The Business Practices Office, March 2009, Hennion Exh. 2, NPCLSV_LIT001344769, at 772.

348 *Id.*

349 Richard Eschle Deposition 32:3-38:19 (Eschle served on a committee that did preliminary review of potential violations prior to referral to BPO; referrals were made to BPO where fact-finding was needed to provide "additional clarity").

Continued on next page

For much of the Review Period, NPC did not devote to investigations of Speaker Program non-compliance, the staff or resources required to complete the investigations it opened. When Mr. Putenis handled compliance matters prior to the establishment of the Ethics & Compliance Department, neither he nor members of his staff conducted investigations[350]; instead, that task was left to various staff in the legal department, Human Resources, and Corporate Security.[351] Though Ethics & Compliance took over this responsibility when it was established in 2003,[352] few people from the Compliance Department were assigned to Investigations between 2004 and 2008.[353] And then, just two years later, a cut to Compliance's budget further limited its ability to carry out investigations.[354] To make matters worse, Navigant found that, even by 2011, NPC did

---

Continued from previous page

349 *See, e.g.*, Michael Shaw email to Maria Woods and preceding email chain, Sept. 6, 2005, NPCLSV_LIT000949513, at 514 (discussing whether to refer potential speaker program violation to BPO, stating "let's consider whether it merely warrants a counseling rather than an investigation"); *see also* Natasha Nelson-Ling Deposition 234:5-238:3 (discussing Nelson-Ling Exh. 7, NPCLSV_LIT001471787, and Nelson-Ling Exh. 8, NPCLSV_LIT001984519; due to a backlog, only the "worst" infractions were sent to BPO, and an "informational only" email was sent out regarding zero-attendee events in 2008, which would not be investigated); Cynthia Cetani Deposition 206:3-207:17.

349 *Id.*

350 Martins Putenis Deposition 35:18-25, 273:14-274:9

351 *See, e.g.*, Maria Woods Deposition 25:3-27:17 (describing other departments which were responsible for investigations, 2005-2008).

352 *See* July 1, 2003 Org. Chart; NPCLSV00018206; Julie Kane Deposition 26:13-25, 29:5-8.

353 Natasha Nelson-Ling Deposition 50:13-52:11 (Maria Woods was the only person under Julie Kane who was doing investigations when Nelson-Ling arrived at Novartis); Novartis "Office of Ethics and Compliance Program Updates," NPC Compliance Network Meeting, Aug. 18, 2004, NPCLSV_LIT003297464, at 466 (showing E&C personnel in 2002-04); CEO/Executive Level Org Charts, 1/1/2002 – 7/1/2011, NPCLSV00018194, at 288 (NPC org charts); Novartis "NPC Internal Investigation Protocol," HRMT Meeting, January 19, 2005, NPCLSV_LIT000814719 at -24 (p.5) (January 2005 presentation listing only Ann Raffensperger and Michael Shaw as the E&C members of the "Core Investigation Group"); Ethics & Compliance, "Investigation Overview: Compliance Departmental Meeting," March 20, 2006, Michael Shaw & Maria Woods, NPCLSV_LIT002531814 at p. 5 (NPCLSV_LIT002531818) (March 2006 presentation listing Julie Kane, Michael Shaw, and Maria Woods as the E&C members of the "Core Investigation Group"). *See also* July 1, 2004, Org. Chart, NPCLSV00018218 through July 1, 2008; Org. Chart, NPCLSV0018251.

354 Natasha Nelson-Ling Deposition 224:10-225:13 (E&C unable to take responsibility for speaker infraction follow-up because the budget for "extra hands" was cut); *see also* "E&C Audits and Investigations" presentation, NPCLSV_LIT000944577 at p. 3 (-44579) ("E&C Audits and Investigations Budget Request for Q2-4 2010," noting that the 2010 budget cuts "reduced work/contractor hours by 4,151 from FY 2009," meaning "[i]nsufficient resources to perform an adequate FF audit" and insufficient investigator resources).

not have a "formal triage process in place…to determine which allegations warrant limited investigatory resources."[355]

Unsurprisingly, Novartis investigations of Speaker Program compliance were frequently left open for years, contributing to a growing and sizable backlog. Within Ethics & Compliance, Maria Woods did most of the investigatory work until Ms. Nelson-Ling and Mr. Hollasch joined NPC in 2008 (around which time Ms. Woods left NPC).[356] Ms. Nelson-Ling testified that when she arrived at NPC, she found a large backlog of several hundred investigations left over by Maria Woods who "was very behind in her investigations" and did not have a good system in place for tracking them and managing the associated documentation.[357] Ms. Nelson-Ling and her team went through hundreds of file folders found in Ms. Woods's office and "one by one . . . to the extent we could investigate them, we did. If we had to close them out because the employees were no longer there, we did."[358] As Julie Kane discussed at her deposition, "[t]here was a time during which [NPC] had a hard time keeping up with the pace of investigations . . . and there were some issues with the way some investigations were being performed."[359] Even in August 2009, E&C's case log shows still listed as "open" 16 cases from 2006, 23 cases from 2007, and 12 cases from 2008.[360]

This backlog seriously hampered the investigations function at NPC. The materials I have reviewed indicate that the frequent, lengthy delays resulted in employees who had committed

---

355 Navigant Report, at 905.

356 *See* Novartis Pharmaceuticals Organizational Charts, NPCLSV00018194 at -8234 to -8245 (showing Maria Woods, AD—Ethics & Compliance, as the only direct report under Michael Shaw); Mark Hennion Deposition 28:5-29:1 (Maria Woods did most of the investigations assigned to Compliance); Natasha Nelson-Ling Deposition 51:4-7 (Maria Woods was in charge of investigations when Nelson-Ling arrived at Novartis).

357 Natasha Nelson-Ling Deposition 50:15-51:18; *see also* David Hollasch Deposition 88:20-89:20 (estimating 50 to 100 backlogged cases when Hollasch took over from Woods).

358 Natasha Nelson-Ling Deposition 51:10-52:22 (Nelson-Ling's team went through file folders and "opened them, read them, investigated them [or] closed them out because the people were gone"); *see also* Natasha Nelson-Ling email to Mark Hennion and Julie Kane, Nov. 3, 2008, NPCLSV_LIT001577601 (concerning Maria Woods's files and "[h]ow…to handle cases where no BPO report was written but a conduct memo was issued" and "case files" that are "sparse or non existent"); Natasha Nelson-Ling and Cheryl Tucker email exchange, NPCLSV_LIT006575230 (concerning Maria Woods's backlogged files).

359 Julie Kane Deposition 177:13-21, 212:21-213:13 (discussing Kane Exh. 12, NPCLSV_LIT001950706); *see also* Mark Hennion Deposition 50:22-51:3 ("[A]t one point in time, and I specifically remember dealing with Maria Woods and Julie Kane, that they appeared to be over their head with cases that were assigned to them . . . I know there was a big delay in a lot of the cases"), 51:25-54:19.

360 *See* E&C Case Log Spreadsheet, NPCLSV_LIT002378627 (spreadsheet showing investigation status for E&C cases from 2006 through 2009, with file name "E&C case log aug 25").

serious compliance infractions avoiding any discipline. In some cases, NPC declined to discipline employees because their misconduct had taken place years earlier.[361] In other cases, the employees left NPC before the conclusion of the investigation into their conduct, and thus never experienced any consequences for such conduct.[362]

Not surprisingly given the staffing, NPC conducted a small number of investigations of Speaker Program-related compliance violations relative to the total number of programs it conducted during the Review Period.[363] The total number of "reported violations" of compliance policies "on all offenses, not just promotional" was 34 for 2004 and 100 for 2005.[364] A draft "Statistical Compliance Overview" by Ann Harmon reported that of the 81 "reports of potential violations of law and policies" received by NPC from October 2004 through March 2005, only one of them related to "meetings/conferences/symposia (Speaker Program[s])."[365] A presentation containing "Internal Investigation Data" for 2004 stated that out of 145 total reported allegations of misconduct, only one related to "HCC: Speaker Programs."[366] Ethics & Compliance case logs indicate they completed 132 (out of 149) investigations in 2006, 204 (out of 227) investigations in 2007, 211 (out of 223) investigations in 2008, and 138 (out of 143) investigations in 2009, and only a fraction of these appear to have been related to Speaker Programs.[367]

---

361 *See, e.g.*, Investigations Spreadsheet, NPCLSV_LIT006563176, at 176 ("Nicole Boss should have received a serious conduct memo or preferably termination for the three violations of policy that she did . . . However, due to the two year delay in taking this case to resolution/close out, at this point, it is recommended that the case be closed without further action.")

362 *See, e.g.*, *id.* at 176 ("closed case because rep's no longer with company"), *id.* at 185 (investigation of Thomas Hopkins with BPO date of 2005 reported as "unsubstantiated 3/25/2009 rep left Novartis on 8/27/2007"); Natasha Nelson-Ling Deposition 52:15-22 (some backlogged investigations were closed out because the people were gone).

363 *See* Expert Report of Richard E. Goldberg, at Table 3.

364 Niral Desai email to Ann Harmon and Maria Woods, March 20, 2008 (concerning total number of cases 2003-2005, with attached charts, NPCLSV_LIT001154529 through NPCLSV_LIT001154539); *see also* Office of Ethics and Compliance: Program Updates, NPC Compliance Network Meeting, Aug. 18, 2004, NPCLSV_LIT003297464, at 467 (reporting that Alertline received 32 calls in 2002, 66 calls in 2003, and 93 calls in the first half of 2004); Michael Shaw email to Elizabeth Henk, May 26, 2005, and prior email chain, (Woods Ex. 1), NPCLSV_LIT000814717, at 742 (draft presentation showing "Internal Investigation data – 2004" counted 145 total "reported concerns" in 2004).

365 Statistical Compliance Overview for period October 1, 2004 – March 31, 2005, April 5, 2005, NPCLSV_LIT000922390, at 392.

366 NPC Internal Investigation Protocol: Awareness Presentation, SLT Meeting, March 16, 2005, NPCLSV_LIT000814734, at 743.

367 *See* E&C Case Log Spreadsheet, NPCLSV_LIT002378627 (spreadsheet showing investigation status for E&C cases from 2006 through 2009, entitled "E&C case log aug 25," of 85 cases between 2006-2009 that were listed on the E&C Closed Cases tab with summaries of the allegations, only 15 are identifiable as related to Speaker Events). See also E&C Case Status Spreadsheet, NPCLSV_LIT000869302 (spreadsheet entitled

Continued on next page

And the Compliance Department largely refused to proactively investigate potential misconduct, instead waiting for an HCP or NPC employee to report misconduct.[368] Instead, Compliance should have opened investigations based upon a reasonable suspicion of non-compliance and made better use of auditing and monitoring, *see supra* Part VI, to proactively identify non-compliant behavior. There were very few such proactive investigations at NPC until 2010. Maria Woods testified that she did not know of any proactive investigations[369] and explained that it would have been atypical to open an investigation without an initial allegation of misconduct.[370] This hobbled Compliance's ability to prevent and detect misconduct.

NPC's reliance on sales representatives and their managers to report misconduct[371] was particularly misguided because those same employees were incentivized to insulate speakers (who were often their customers) because prescription activity affected their sales numbers and compensation. Compliance was aware that sales associates would frequently "fail to catch" speaker infractions,[372] and also of instances where sales representatives and managers appeared to have been complicit[373] in blatant speaker infractions or other patterns of activity presenting anti-kickback risks. As the 2011 Navigant Report found, "line managers in the field were not always using the Field Coaching Report for documenting compliance violations, for fear of triggering an

---

Continued from previous page

"E&C Case Status – 4-23-10," showing total number of opened and closed cases for 2009 and separately for 2010).

368 Julie Kane Deposition 140:9-142:7 (an "investigation" required some alleged misconduct); Maria Woods Deposition 66:16-67:11 (not typical to open an investigation without a complaint or allegation of a particular misconduct); *see also* Natasha Nelson-Ling Deposition 154:15-157:10, 208-09 (Beth Margerison sometimes brought Nelson-Ling spreadsheets indicating potential issues that she found in the Concerto data, which would be investigated).

369 Maria Woods Deposition 65:4-67:11.

370 *Id.* at 66:24-67:11, 74:3-13.

371 "Speaker Infractions" slide deck, June 17, 2010, NPCLSV_LIT001347846, at 855-56 (lead sales representative is responsible for monitoring, documenting and reporting speaker infractions on-site).

372 David Hollasch Deposition 277:10-23.

373 *See* 2008 Audit Presentation, at 480 (19% of programs had non-HCP relative of the speaker or another participating HCP attending); *see also id.* at 477; Natasha Nelson-Ling Deposition 139:6-140:12; David Hollasch email to Rebecca Miller, Feb. 5, 2010, "Re: Dr. [redacted] Programs," NPCLSV_LIT001574885 (Hollasch Exh. 13) (analyzing repeat attendees at Dr. [redacted] programs, including Dr. [redacted] wife [redacted], who is not a nurse but is sometimes listed as a nurse for attendance purposes); David Hollasch Deposition 265:12-267:12 (regarding Dr. [redacted] surprise audit); "Corporate Security Investigation Report, BPO Case 287/2007, May 18, 2007, NPCLSV_LIT003602748 (finding repetitive events with Dr. [redacted] paid to present, representative had close personal relationship with [redacted], same five HCPs present each time, coincide with dramatic rise in [redacted] prescription habits, conclude no policy violation but closer review of program risk recommended); Speaker Utilization Management Report, January 19, 2010, NPCLSV02748638 at -8651 (showing [redacted] still listed as a Tier 2 speaker).

investigation."[374] NPC was also aware that sales representatives were afraid to report non-compliance that they observed for fear of retaliation. *See supra* Part V. Relying on sales representatives and their managers for compliance reporting was an ineffective control mechanism.

Even when presented with allegations that Speaker Programs were systematically being used to bribe doctors, Compliance refused to launch an investigation. Posts on the online message board CafePharma in 2006 by self-identified Novartis sales representatives described NPC's "PILs" programs[375] as a "way for Novartis to PAY its prescribers in hope that they will compensate Novartis with scripts" and described the routine falsification of event records by NPC employees.[376] I did not see evidence that Compliance investigated these (or similar CafePharma posts).[377] Soon after, Ms. Woods was assigned to investigate two district managers who conducted a PILs program that had no attendees after another NPC employee complained.[378] In an email regarding another PILs investigation, Ms. Woods made the connection between her specific investigation and the broader issue reported on CafePharma, writing, "this issue is of particular concern given some recent chatter on NPC's Cafepharma site deriding PILs programs as 'smokescreens for building rapport and doing PR and paying customers.'"[379] In my opinion, in response to the CafePharma posts, which suggested widespread misconduct, Compliance should

---

[374] Navigant Report, at 897, 906, 949.

[375] "PILs" is an acronym for Practice Integrated Learnings, a type of speaker meeting where two HCPs joined together to provide integrated information. If there was more than one paid speaker, the September 1, 2010 Compliance Policies provided there must be three HCPs in attendance for each speaker. *See, e.g.*, 2010 E&C Policies § 7.06, "Attendance Criteria" ("Speaker Programs are expected to have at least three Prescribers in attendance … for each Speaker," emphasis in original).

[376] Maria Woods Deposition 61:1-62:25 (discussing CafePharma post alleging that Novartis was using PILs as a means of paying its prescribers, which would be a violation of Novartis policies, as well as suggestions to hit "all attendees" even if they did not all attend); *see also* Maria Woods e-mail to Michael Shaw, February 23, 2006, Woods Exh. 5, NPCLSV_LIT000082030, at 035 (CafePharma posting about PILs).

[377] Maria Woods Deposition 63:1-67:3 (Woods does not recall the CafePharma post and does not know whether it was investigated, nor does she recall if there were any proactive investigations relating to speaker program compliance); *see also* "Closed/Substantiated Compliance Cases – January – September 2005," NPCLSV_LIT006656812, Woods Exh. 4 (Woods' record of closed compliance cases).

[378] *See* Maria Woods Deposition 96:12-98:19; Maria Woods email to Michael Shaw, Feb. 24, 2006, NPCLSV_LIT00092155 (Woods Exh. 6) (BPO notification regarding a PILs issue where two representatives held two PILs programs in a single night at the same restaurant with the same attendees); *see also* Maria Woods email to Ross Volk, June 27, 2006, NPCLSV_LIT001543332 (Woods Exh. 9) (discussing an investigation performed by two DMs who independently looked into an issue where sales representatives hosted two PILs events on the same night, with the same attendees).

[379] Maria Woods email to Michael Shaw, Feb. 24, 2006, and prior email chain, NPCLSV_LIT000921555 (Woods Exh. 6); *see also* Maria Woods Deposition 74:17-75:21 (discussing a PILs program where only the speaker attended), 77:20-78:19.

have conducted a broader review of NPC's PILs programs and investigated any employees who, based on that review, it reasonably suspected of misconduct. There is no indication that this happened; instead it appears that NPC limited its response to the investigation of those two managers.

Similarly, when a 2008 investigation of a sales representative identified abuse of Speaker Programs indicated by repeat attendance, Novartis failed to conduct a broader investigation of the issue. In a 2008 email Ms. Woods informed Julie Kane that a recent investigation into a sales representative hosting "fraudulent Speaker Programs" found no evidence that that representative directly violated NPC policy, but did find evidence of "repetitive programs involving the payment of honoraria with the same speakers and attendees, which coincides with a dramatic increase in the speaker's prescription writing habits."[380] The investigation report recommended that Sales Management, the Legal Department and/or Compliance perform a closer review to gauge any possible risk.[381] But nothing in the materials indicated that this recommendation was followed.[382] Rather, Compliance continued to permit repetitive programs through the entire Review Period, *see supra* Part II, and NPC's Compliance Officers testified that they did not see repeated attendance at Speaker Programs as a serious concern.[383]

Nor did NPC conduct these investigations in a manner designed to identify and address program-wide compliance risks. In December 2011, Navigant concluded that NPC's investigations of potential compliance violations resulted in BPO reports that were "merely a recitation of the facts that were uncovered during the investigation without the benefit of additional analysis" and that if RC meetings included discussion of root causes, this was not documented.[384]

And the Compliance Department repeatedly failed to adequately investigate the few reports of misconduct it did receive. For example, in March 2006, Compliance learned that a sales representative, Tim Murtha, had arranged for a Dr. [redacted], described by Mr. Murtha as a "high prescriber," to be taken off the waiting list for speaker training. In Ms. Kane's view, this did not warrant investigation unless the intent was to reward the physician for being a high prescriber,

---

380 *See* Maria Woods email to Julie Kane, Jan. 15, 2008, NPCLSV_LIT006815186 (Woods Exh. 19); *see also* Maria Woods Deposition 149:7-152:14 (discussing Woods Exh. 19); Sales Representative Brent (Ben) Watson Speaker Fraud Case, BPO Case 287/2007, May 18, 2007, NPCLSV_LIT003602748, at 750 (BPO report showing that one speaker, Dr. [redacted], was paid over $63,000 between Jan. 2006 to Sept. 2007 to present at 68 Speaker Programs that were attended in most cases by the same five HCPs).

381 *See* Maria Woods email to Julie Kane, Jan. 15, 2008, NPCLSV_LIT006815186 (Woods Exh. 19); *see also* Maria Woods Deposition 151:9-153:12 (discussing potential compliance concerns based on repeat attendance).

382 *See* Julie Kane Deposition 53:2-13.

383 Cynthia Cetani Deposition 33:9-36:1; Julie Kane Deposition 50:18-53:17, 55:19-25.

384 Navigant Report, at 904.

and in her deposition she applauded Michael Shaw for "working with the business" by directly approaching Mr. Murtha for clarification of his intent.[385] NPC excused Murtha's email as "remarks [that] were not carefully written" and accepted his revised explanation that he "intended to indicate that the physician's attendance at speaker training would result in a trained speaker who will eventually persuade others to use Novartis products."[386] An effective Compliance Officer would have done more than talk to the sales associate and simply accept his statement of intent; the e-mail was sufficiently concerning that a more robust investigation was warranted. The Compliance Department should have looked at Mr. Murtha's Speaker Program data and Dr. [redacted] prescribing behavior to determine whether there was a pattern that violated the one purpose rule. Similarly, Compliance did not organize any investigative response to the Chyung Report, *see supra* Part III, after learning that modest meal limits were being exceeded about 25% of the time.[387] Compliance should have identified and investigated the employees involved and should have considered whether the pattern indicated a larger compliance problem.

NPC's processes for investigating misconduct by speakers and responding to "speaker infractions"[388] were also deficient. Before the CIA, speaker evaluations were not reviewed by Compliance but by Sales Operations.[389] There was no follow-up process if a sales representative noted on a speaker evaluation form that a speaker failed to meet compliance requirements, and it was uncommon for Compliance to investigate speaker infractions.[390] Not until 2009 did Compliance develop processes to deal with speaker issues, including levels of corrective action ranging from a warning for the first infraction to escalation through Compliance and Legal that could "potentially inactivate the speaker or terminate [the] contract."[391] It appears that this process did not go into effect until September 2010, however,[392] and when it did, there was "a lack of agreed upon guiding principles for specific correction actions that should be assigned to

---

385 At her deposition, Julie Kane held out this situation as "a really good example of how the compliance program was working with the business to ensure we were handling these kinds of things properly". See Julie Kane Deposition, 148:21-24; see also 146:13-156:22; discussing Michael Shaw email, March 6, 2006, NPCLSV_LIT000203872, Kane Exh. 8.

386 Spreadsheet showing the outcomes of various investigations, NPCLSV_LIT007219366, at 370.

387 Julie Kane Deposition 161:14-164:13 (discussing Kane Ex. 9, NPCLSV_LIT006663781).

388 "Managing Speaker Issues" slide deck, October 12, 2009, NPCLSV_LIT000069254, at 257.

389 Cynthia Cetani Deposition 114:10-120-11.

390 David Hollasch Deposition 270:16-273:24, 274:12-277:23.

391 "Managing Speaker Issues" slide deck, October 12, 2009, NPCLSV_LIT000069254, at 258.

392 *See* Lisa Ippoliti email to Cynthia Cetani, March 4, 2011, (Ippoliti Exh. 10) NPCLSV_LIT000969444, at 446 (slides regarding the Speaker Infractions and Appeals process; formal Infractions Process was established in Sept. 2010).

the speaker to address the speaker infraction."[393] The process was cumbersome because it required sales representatives to report information to AHM, which in turn reported back to NPC. Additionally, on the NPC side, the process was simultaneously managed by both Ethics & Compliance and the Compliance Quality and Controls group.[394] In March 2011, the formalized speaker infraction investigation process was moved exclusively to Ethics & Compliance based on a recommendation to "[e]stablish one single & consistent owner of Investigations."[395]

B. CONSISTENCY OF DISCIPLINE

NPC did not consistently apply standards and impose discipline for violations of Compliance Policies. In 2005, NPC established the RC as a means of fostering consistency in discipline for substantiated compliance breaches and other misconduct. At RC meetings, Compliance, Legal, Human Resources and business units would come together at the end of an investigation to recommend what discipline to impose (if any).[396] However, in my opinion, the RC was not very effective as a control to ensure consistency of discipline because Sales Management had the ability to overrule the RC's decisions.[397]

---

393 Compliance, Quality & Controls (CQC), "Considerations for Addressing Speaker Infractions," January 2011, NPCLSV_LIT000002282, at 283.

394 *See, e.g.*, "Managing Speaker Issues" slide deck, October 12, 2009, NPCLSV_LIT000069254; Lisa Ippoliti Deposition 202:12-204:2 (formal infraction process was put in place in September 2010 and managed by CQC), 205:1-207:9; Lisa Ippoliti email to Cynthia Cetani, March 4, 2011, NPCLSV_LIT000969444, at 446 (Ippoliti Exh. 10) (slides regarding the Speaker Infractions and Appeals process; CSO and E&C both manage the formal Infractions Process established in Sept. 2010); "Marketing Speaker Program: Audit Remediation Plan-of-Action," Internal Summary of Remediation and Process Changes, Jan. 28, 2010, NPCLSV_LIT001574844, at 871.

395 Lisa Ippoliti Deposition 205:7-207:9 (from September 2010 speaker infractions were investigated by Shauna Liu in CQC, then this was moved to E&C to ensure consistency and competence), 216:17-218:20 (recommendation to move investigations from CQC to E&C in order to have one consistent owner of all investigations).

396 Natasha Nelson-Ling Dep. 213:14-214:19 (the RC voted on a proposed outcome for any substantiated investigation, and management made the ultimate decision); Maria Woods Deposition 84:22-89:5 (various parties from HR, legal, and compliance met to determine whether to issue a conduct memo following an investigation into a violation).

397 Natasha Nelson-Ling Deposition 214:12-19 (RC outcomes were mere recommendations to management, who decided how to respond to an infraction), 219:12-220:15 (E&C had no power to discipline, only to recommend it - whether to fire someone was determined and implemented by Sales Management and HR, E&C was not privy to those conversations); *see also* Ethics & Compliance, draft "Internal Investigations Reference Guide," June 2009, NPCLSV_LIT000816783, at 785 (describing the "12 Step Investigation Process," including "9. HRBP apprises Management of the Resolution Committee's evaluation of facts and disciplinary/corrective action…Management decides whether to follow the recommendation."), and at -

Continued on next page

There were no written guidelines for discipline; rather, NPC attempted disciplinary consistency by using the same team of decision-makers.[398] However, because management could overrule the regular members of the RC, whose Compliance representatives were not involved in determining whether their recommended outcomes were carried out,[399] the RC was not effective at ensuring consistent discipline for compliance breaches.[400] The Navigant Report from December 2011 concluded that NPC was only "[p]artially" successful at "consistently undertak[ing] appropriate disciplinary action across the company."[401] The report stated that "there are at times disciplinary results that are less consistently applied, especially as it relates to no-termination cases." The report also noted that NPC had "no guide or Disciplinary Action Model that provides guidance as to the appropriate type of sanction" in response to non-compliance, and recommended that NPC establish clear guidance on potential disciplinary actions.[402] In response to Navigant's findings, NPC management stated that it planned to develop protocols related to the investigations process to "help ensure greater consistency" by March 31, 2012.[403]

Finally, NPC's Speaker Program policies made imposing discipline more difficult than necessary. For much of the Review Period, NPC's policies were unclear and this inhibited investigations and discipline because questionable conduct was open to subjective evaluation after-the-fact.[404] In other words, NPC found it difficult to discipline a sales representative for violating a policy

---

Continued from previous page

6787 ("If management disagrees with the findings or recommendation, management discusses the case with the Resolution Committee until agreement is reached.").

398 Maria Woods Deposition 93:14-95:9 (three consistent investigators made determinations and attempted to keep track of discipline imposed in prior cases).

399 *See* Natasha Nelson-Ling Deposition, 214:17-215:18 (management could override the RC decision, she was not involved in that, no recollection of whether this happened but is sure it did, doesn't know how frequently RC recommendations were actually implemented).

400 I also saw evidence that a sales representative's history and success as a salesperson could be factored into decisions about discipline for compliance breaches. *See, e.g.,* Spreadsheet of Cases Stated or Concluded in 2004 and in 2005, NPCLSV_LIT000922389 (spreadsheet sent via email on May 27, 2005, containing HR cases that were investigated in 2004 and 2005 that includes for each employee under investigation the employee's performance rating for the past two years, in 2002 and 2003).

401 Navigant Report, at 900.

402 *Id.* at 900-01.

403 *Id.* at 952.

404 Natasha Nelson-Ling Deposition 62:21-65:5 (policies were too vaguely worded, open to interpretation), 105:17-108:21 (gaps in definitions in policies made it hard to identify compliance with AKS), 135:3-138:11 (policies were imprecise enough to allow interpretation that permitted programs on fishing boats, which was inappropriate).

that was unclear or did not exist.[405] The lack of clear guidance on "occasional meals," cancelled programs, repeat attendance, the length of a speaker's presentation, and other issues protected the sales representatives and their managers from investigative scrutiny and punishment for misconduct.[406] Given the push-back from the field and senior management to proposals that managers become more accountable for Speaker Program expenses and close-out reports after the Q3 2008 Compliance Audit,[407] the lack of definition worked in favor of the sales associates and managers.[408] NPC's failure to reliably discipline employees for compliance breaches communicated a message that non-compliance was sometimes acceptable or at least, non-punishable.

VIII. Responding to Detected Problems and Undertaking Corrective Actions

The OIG identifies the ability of the Compliance Officer or management to act immediately upon receipt of "reasonable indications of suspected noncompliance" as an additional element of an

---

[405] *See, e.g.*, BPO Pro Forma Information Report, BPO Number 514/2009, Aug. 2, 2009, NPCLSV_LIT001184860, at 863 (BPO Report for Jennifer Weed regarding four meals with HCPs where documentation was missing or had discrepancies; the report notes that "Jennifer came across as only somewhat truthful," and the allegations of modest meal and violations regarding sign-in sheets were substantiated, but the recommended action was "training" and that it "may be appropriate for her to receive an oral or written warning.")

[406] *See* Martins Putenis e-mail to Maria Woods, September 6, 2005, "Re: Compliance Question," NPCLSV_LIT000993591; David Hollasch Deposition 105:2-106:7 (no definition for "occasional" meals allowed one rep to have 22 meals in one month with the same doctor), 109:22-110:6 (no minimum time for educational portion of speaker program), 120:12-121:23, 144:16-146:15; Novartis Ethics & Compliance, Policy in Practice Communications, Marketing Communication #1, "Guidelines for Occasional Meals with HCPs and Other Customers," September 17, 2009, NPCLSV_LIT001579190 (does not define "occasional").

[407] *See* Audit Remediation: RD-FLM, September 2009, August 28, 2009, NPCLSV_LIT002518914; *see also* Audit Remediation Plans: Audit of Sales Representatives Interactions with HCP: Leadership Overview, August 28, 2009, NPCLSV_LIT002518879. The review materials include examples of minor sanctions, such as verbal counseling or a conduct memo, being given out in response to intentional Speaker Program non-compliance. *See, e.g.*, BPO Number 17/2007, NPCLSV_LIT001206257 at 259 (recommending conduct memo for representative who hosted holiday party at bowling alley); BPO Number 477/2006, NPCLSV_LIT001205990 (representative held happy hour at Hooters and expensed it as a Roundtable given conduct memo); Conduct Memo to Scott Collett, Aug. 8, 2007 (falsifying documentation of multiple events).

[408] David Hollasch Deposition 144:16-146:15, 147:5-25, 151:9-152:13, 167:21-168:15, 222:3-223:22, 247:4-249:11 (concern NPC was taking "baby steps" and "sugarcoating" issues instead of taking drastic corrective action needed), 250:19-252:15 (corrective actions "dragged on" rather than being done immediately), 309:3-310:9.

effective compliance program.[409] The OIG advises that the response following an investigation should include a corrective action plan addressing the root cause of the problem, a report and repayment to the government, and/or a referral to criminal or civil law enforcement authorities.[410] The amount of a monetary loss to a federal health care program is not determinative of whether conduct should be reported. In fact, there may be instances where there is no readily identifiable monetary loss but corrective actions are necessary to protect the integrity of health care benefits programs.[411]

When a Compliance Officer discovers credible evidence of misconduct from any source, and after a reasonable inquiry, believes it may violate criminal, civil or administrative laws, the company *must* report the misconduct to appropriate federal or state authorities within a reasonable period but not more than 60 days after determining there is credible evidence of a violation.[412] Prompt voluntary reporting demonstrates good faith and a willingness to correct the problem. Reporting the problem is considered by the OIG in determining whether to impose administrative sanctions (*e.g.,* penalties, assessments or exclusion) and by courts in imposing penalties.[413]

The pharmaceutical manufacturer should provide all relevant information and describe the potential financial impact when reporting. The Compliance Officer, under advice of counsel and with guidance from the government, may continue investigating. If the investigation reveals that criminal, civil, or administrative violations have in fact occurred, the Compliance Officer should notify the appropriate governmental authority of the outcome and its impact on applicable federal health care programs or beneficiaries. Some violations are so egregious that they warrant immediate notice to the government prior to, or simultaneously with, an internal investigation.[414]

Findings:

- **NPC had no written process for responding promptly to detected misconduct involving Speaker Programs.**
- **NPC did not go far enough in immediately undertaking corrective actions in response to control gaps.**

---

409 OIG Guidance, at 23742.

410 *Id.*

411 *Id.* at 23743.

412 *Id.* at 23742.

413 *Id.* at 23732.

414 *Id.* at 23743.

A. NO WRITTEN STANDARDS ON REPORTING VIOLATIONS

NPC's policies contained no written guidance explaining that management or the Legal or Compliance Departments had an obligation to promptly respond to detected violations of law, to investigate and determine corrective actions, and to report certain violations to the government or an administrative agency.[415] For example, the 2006 Ethics & Compliance Policies stated that employees should report any actual or perceived violations so they could be investigated and addressed,[416] outlined the duty to report compliance issues to managers and to Compliance,[417] but included no information about management's duty to report to the appropriate agency any behavior that violated criminal, civil or administrative laws. The duty to report was not clarified in later written standards which included little written guidance about how to identify and track non-compliance, report it promptly and follow up with corrective actions.[418] The policies should have explained management's obligation to report violations as part of emphasizing the Compliance Program's importance.[419] Only the CIA's requirement that NPC disclose "Reportable Events" to the government finally changed this.[420]

NPC's handling of the Nevada Audit, *see supra* Part VI, demonstrated its unwillingness to report violations to a government as required by law. Nevada law required, among other things, annual audits to monitor the company's compliance with its Code.[421] Speaker Program non-compliance in Nevada was observed during the Nevada Audit.[422] Ms. Nelson-Ling characterized internal controls over sales representatives' interactions with Nevada HCPs as "unsatisfactory" but NPC changed this finding to "satisfactory" because of concerns about Nevada state regulators' reaction to an "unsatisfactory" assessment.[423] If the internal controls on speaker programs were in fact "unsatisfactory," the certification to Nevada regulators that the controls were "satisfactory" demonstrates that NPC was not ready to honestly report to regulators.

---

415 *See e.g.*, 2003 Guidelines §§ 3-1, 4-1, 4-2; 2004 Guidelines §§ 1-1, 1-2, 3-5, 5-1 through 5-5.

416 *See* 2006 Guidelines, at 969.

417 *Id.* at 1023.

418 *See, e.g.*, NPC Code of Employee Conduct, 2007, NPCLSV00014593; Code of Conduct: Values to Live by, 2010, NPCLSV00015252.

419 *See* David Hollasch Deposition 247:4-249:11; *see also id.* at 251:8-252:15.

420 *See* OIG-NPC Corporate Integrity Agreement, Sept. 28, 2010, NPCLSV_LIT001009931, at 955

421 Nevada Marketing Code of Conduct; AB123, June 14, 2007; NRS 639.570; *see* https://s3-us-west-2.amazonaws.com/porzio/media/1074/pharma-alert-6-18-07.pdf; and http://bop.nv.gov/uploadedFiles/bopnvgov/content/Resources/ALL/Annual_Certification_Manufacturers_Wholesalers.pdf.

422 David Hollasch Deposition 194:12-195:5.

423 *Id.* at 187:4-188:25.

B. INSUFFICIENT CORRECTIVE ACTION IN RESPONSE TO NON-COMPLIANCE

In July 2009, NPC responded to the findings of the Q3 2008 Compliance Audit by planning changes to the Compliance Policies and making "Corrective Action Plans."[424] These plans included improved FLM monitoring of representatives, greater sales representative responsibility over fiscal controls and documentation of issues at Speaker Programs. The Compliance Department outlined a time-table to implement these corrective actions by October of 2009.[425]

In my opinion, the proposed corrective actions did not go far enough to respond to the risk and, in any case, were not even fully implemented by the October deadline.[426] Compliance recommended updating speaker contracts with performance-related clauses and creating a Speaker Program Implementation Guide with a checklist for speaker issues.[427] These corrective actions, while helpful steps, did not cure the Speaker Program compliance gaps—vague compliance policies, insufficient monitoring and too few and no pro-active investigations.

In 2011, Pricewaterhouse Coopers, the IRO retained pursuant to the CIA to assess NPC's "systems, processes, policies, and procedures (including the controls on those systems, processes, policies, an procedures)" for the CIA's First Reporting Period, September 29, 2010, through September 28, 2011, reported that there were a number of control gaps related to Speaker Programs. The IRO could not confirm compliance with Speaker Program policies because crucial documents were missing.[428] The IRO also noted the Event Alliance and Encore systems did not have a field to allow the sales associate to explain why an event went forward when there were fewer than three legitimate attendees or HCPs present.[429]

The IRO also found instances in which NPC did not take corrective action following reported non-compliance.[430] The IRO reviewed control documents regarding 50 randomly sampled HCPs who had received payments from NPC between October 1, 2010, and March 31, 2011.[431] The

---

424 Corrective Actions Plans, Audit of Sales Representatives' Interactions with HCP: Leadership Overview, July 2009, NPCLSV_LIT001245621.

425 *See* Julie Kane Deposition 332:19-333:18 (discussing Kane Exh. 24, NPCLSV_LIT00045144).

426 "Managing Speaker Issues," October 12, 2009, NPCLSV_LIT000069254.

427 Cynthia Cetani Deposition 314:10-319:19 (discussing speaker performance monitoring checklist); 2008 Audit Presentation, at 478 (recommending a checklist for lead representative to guide review of speaker performance for compliance and contracts be updated to include clauses addressing speaker non-compliance); "Managing Speaker Issues," October 12, 2009, NPCLSV_LIT000069254, at 259.

428 IRO Report, at 8111, 8117, 8119.

429 *Id.* at 8120.

430 *Id.* at 8116.

431 *Id.* at 8110-11.

IRO tested to see whether the control documents were available, whether the speaker had a signed consulting agreement, whether the HCP's honorarium exceeded fair market value, whether the Speaker Program met attendance criteria, whether the Speaker Monitoring Checklist was completed, and whether Field and Marketing Services were informed of any speaker's failure to follow NPC's policies.[432]

The IRO's findings indicated that at the time of the review, NPC did not yet have a robust method of implementing corrective action after reporting compliance breaches. For example, on March 3, 2011, an HCP received payment for a Speaker Program for which he had failed to show up. The speaker infraction process was not followed—NPC could not demonstrate any corrective action related to this specific payment.[433] The IRO also found that NPC failed to seek recoupment of an overpayment to an HCP for a Speaker Training Web Conference. There was no corrective action initiated in response to this.[434]

[432] *Id.* at 8112.

[433] *Id.* at 8115-16.

[434] *Id.* at 8117-18.

VIRGINIA B. EVANS, ESQ.

EXPERIENCE

Virginia B. Evans, LLC, Charlottesville, VA **2016 – Present**
Owner, Managing Partner

- Consulting services for health care clients regarding a broad range of regulatory and legislative issues, including compliance under the Affordable Care Act (ACA), Stark Law and Anti-Kickback Statute
- Practice focuses on fraud and abuse issues, including development and implementation of corporate compliance programs, internal reviews and investigations, and federal and state governmental investigations arising from False Claims Act, Stark Law, and Anti-Kickback Statute actions
- Clients include private healthcare entities and governmental agencies

Centra Health, Inc., Lynchburg, VA **2012 – 2015**
Vice President, General Counsel & Corporate Compliance Officer

- Created Legal & Compliance Department for a $750 million hospital system with four hospitals, post-acute care, skilled nursing facilities, surgical centers, a large physician practice, two insurance companies, and specialized schools
- Counsel to Board of Directors and management on legal, regulatory and compliance issues
- Provided expert guidance to Board Audit and Compliance Committee, Finance Committee, and Executive and Physician Compensation Committee
- Provided legal advice for reorganization of Board of Directors, drafted Code of Conduct and Compliance Plan and standardized Physician Recruitment and Physician Employment Contract templates for regulatory consistency
- Provided legal guidance on commercial, anti-trust and patient privacy issues during formation of Clinically Integrated Network (CIN) and acquisition of a hospital, an insurance company, and several practices

Ober, Kaler, Grimes and Shriver, Washington, DC **2010 – 2012**
Shareholder/Partner, Health Care Practice

- Practice focused on government regulatory and white-collar defense, legal and compliance guidance to health care providers and pharmaceutical companies, internal investigations, voluntary disclosures, grand jury practice, and response to allegations of misconduct
- Conducted criminal, civil and administrative defense and litigation, including under state and federal False Claims Act, Stark Law, and Anti-Kickback Statute

Daylight Forensic & Advisory LLC, Washington, DC **2007 – 2010**
Managing Director, Health Care Practice

- Managed health care forensic practice and academic medical center initiatives
- Trained international clients on Foreign Corrupt Practices Act (FCPA)
- Designed audits and investigations of organizations including large hospital systems, government agencies, and national retail pharmacy chain

KPMG, LLP, Washington, DC **2005 – 2007**
Director, Forensic Services, Mid-Atlantic Health Care Channel Leader

- Conducted fraud investigations, Independent Review Organization (IRO) engagements and compliance/fraud risk assessments for health care systems, hospitals, pharmaceutical, and durable medical equipment companies
- Investigated allegations of misconduct during the audit process (Shadow Audits), provided training on FCPA, SOX 404, and regulatory compliance

United States Attorney's Office, District of Maryland **1991 – 2005**
Chief, Civil Division (2004-2005); Deputy Chief, Civil Division (2004-2005); Civil Health Care Fraud Coordinator (2001-2005); Public Affairs Officer (2001- 2003); Insurance Fraud Coordinator (1992 – 2001); Criminal Health Care Fraud Coordinator (1993 – 1997)

- As Civil Chief, supervised all civil investigations, litigation, and settlements on behalf of United States including False Claims Act and Stark Law cases, and managed budget and priorities

- Conducted civil and criminal trials and litigation in District Court and in Fourth and Second Circuit Courts of Appeals
- Engaged in civil defensive litigation including employment discrimination, medical malpractice, FOIA and Privacy Act, and Federal Tort Claims Act cases
- Investigated and prosecuted complex crimes, including in health care, financial institution and defense contracting fraud, computer crimes, racketeering, drug diversion, and extortion

United States Attorney's Office, Eastern District of New York **1987 – 1991**
Assistant United States Attorney

- Investigated and prosecuted criminal matters involving financial institution fraud, securities fraud, insurance fraud, income tax fraud, narcotics importation and distribution, and money laundering

United States Department of Justice, New Orleans, LA **1979 – 1986**
Trial Attorney, Organized Crime and Racketeering Section

- Investigated and prosecuted criminal matters involving racketeering, extortion, obstruction of justice, perjury, narcotics, bank robbery, embezzlement, insurance fraud, gambling, and political corruption

PROFESSIONAL AWARDS

Department of Health & Human Services, Office of Inspector General, Integrity Award, 2006

Gary P. Jordan Award for Outstanding Dedication Exemplifying Finest Level of Public Service, District of Maryland United States Attorney's Office, 2002

United States Attorney General's Award for Sustained Superior Performance, 1990

United States Attorney General's Special Commendation Award for Distinguished Service,1985

SELECTED LECTURES AND PUBLICATIONS

American Bar Association, Health Law Section, Health Litigation Interest Group, HLBytes, *Ransomware Attacks Against Hospitals on the Rise*, April 2016

American Bar Association, Health Law Section, Health Litigation Interest Group, HLBytes, *Enhanced HIPAA Enforcement Likely in 2016*, December 2015

American Health Lawyers Association; *Understanding the Use of Misdemeanors in Health Care Enforcement*, AHLA Connections Magazine, March 2012

Health Law and Compliance Update 2012, Chapter 2, *Voluntary Disclosures; A Guide for the Health Care Executive*, Wolters, Kluwer, January 2012

Ober|Kaler, Oberview, "*Objection, Privilege": Protecting the Attorney Client Privilege amidst the Shifting Sands of False Claims Act Jurisprudence*, December 18, 2011

Ober|Kaler Health Law Alert, *Seeking Shelter during Uncertain Times: Assessing the Federal Quality Assurance Privilege*, Issue 6, 2011

Ober|Kaler Health Law Alert, *Compliance with the Elder Justice Act's Reporting Requirements: Cautionary Tactics in the Face of Continuing Uncertainty*, June 14, 2011

Medical Lab Observer, *Take Steps to Prevent Spoliation when Using Electronic Records*, June 2011

Medical Lab Observer, *Form an Effective Compliance Program*, January 2011

American Health Lawyers Fraud and Abuse Practice Group Alert, *The Justice Department Turns Up the HEAT on Alleged Medicare Fraud in Detroit*, July 7, 2009

STATE BAR ADMISSIONS & PROFESSIONAL ASSOCIATIONS

- Virginia (to be sworn in July 2017), New York, Pennsylvania, Maryland, and Louisiana
- Virginia Corporate Counsel
- Certified in Healthcare Research Compliance (CHRC)
    - Served on Institutional Review Board (IRB)
- American Bar Association, Litigation Risk Interest Group
- American Health Lawyer's Association, Fraud & Abuse Section
- Health Care Compliance Association

EDUCATION

NEW YORK UNIVERSITY SCHOOL OF LAW, New York, NY
LL.M., Taxation, 1987

TULANE UNIVERSITY, New Orleans, LA
JD, 1978

- Senior Fellow
- Federal Student Clerkship: Judge Frederick J. R. Heebe, E.D. of LA, 1997 - 1978.

LAFAYETTE COLLEGE, Easton, PA
BA, *cum laude*, Art History, 1975

APPENDIX B

Documents Considered in Addition to those Cited in the Report

Deposition Testimony (including all deposition exhibits):

Deposition of Michael Beck, October 20, 2016
Deposition of Kathy Bronshtein, October 24, 2016
Deposition of Cynthia Cetani, September 30, 2016
Deposition of Richard Eschle, October 27, 2016
Confidential Deposition of Alex Gorsky, March 7, 2017
Deposition of Mark Hennion, October 25, 2016
Deposition of David Hollasch, November 29, 2016
Deposition of Lisa Ippoliti, October 7, 2016
Deposition of Mark Iwicki, October 19, 2016
Deposition of Julie Kane, October 18, 2016
Deposition of MeiHsiu Lin, October 28, 2016
Confidential Deposition of Beth Margerison, October 17, 2016
Deposition of Natalie Nelson-Ling, October 21, 2016
Videotaped Deposition of Lisa Pilla, January 10, 2017
Deposition of Noah Puckowitz, December 8, 2016
Deposition of Martins Putenis, October 26, 2016
Deposition of Paul Rabideau, October 27, 2016
Deposition of Gregory Schofield, December 16, 2016
Deposition of Karen Sorensen, February 24, 2017
Deposition of Mark Tramposch, February 28, 2017
Deposition of Maria Woods, October 28, 2016

Produced Documents, by Bates number:

NPCLSV_LIT000000011
NPCLSV_LIT000014044
NPCLSV_LIT000033079
NPCLSV_LIT000082150
NPCLSV_LIT000105725
NPCLSV_LIT000135941
NPCLSV_LIT000159893
NPCLSV_LIT000200279
NPCLSV_LIT000201666
NPCLSV_LIT000201668
NPCLSV_LIT000201827
NPCLSV_LIT000201831
NPCLSV_LIT000204352
NPCLSV_LIT000205450
NPCLSV_LIT000205645
NPCLSV_LIT000209388
NPCLSV_LIT000276050
NPCLSV_LIT000364364
NPCLSV_LIT000395829
NPCLSV_LIT000395834
NPCLSV_LIT000449361
NPCLSV_LIT000451288
NPCLSV_LIT000501959
NPCLSV_LIT000502078
NPCLSV_LIT000502081
NPCLSV_LIT000502466
NPCLSV_LIT000503321
NPCLSV_LIT000547070
NPCLSV_LIT000547081
NPCLSV_LIT000547086
NPCLSV_LIT000547114
NPCLSV_LIT000547159
NPCLSV_LIT000554672
NPCLSV_LIT000554675
NPCLSV_LIT000745844
NPCLSV_LIT000750311
NPCLSV_LIT000750355
NPCLSV_LIT000755000
NPCLSV_LIT000762588

NPCLSV_LIT000769383
NPCLSV_LIT000773929
NPCLSV_LIT000780592
NPCLSV_LIT000799033
NPCLSV_LIT000806270
NPCLSV_LIT000819189
NPCLSV_LIT000819190
NPCLSV_LIT000844016
NPCLSV_LIT000852989
NPCLSV_LIT000854741
NPCLSV_LIT000857895
NPCLSV_LIT000869041
NPCLSV_LIT000875752
NPCLSV_LIT000886432
NPCLSV_LIT000886556
NPCLSV_LIT000890892
NPCLSV_LIT000907095
NPCLSV_LIT000916634
NPCLSV_LIT000921351
NPCLSV_LIT000923292
NPCLSV_LIT000925524
NPCLSV_LIT000934564
NPCLSV_LIT000944575
NPCLSV_LIT000944577
NPCLSV_LIT000944596
NPCLSV_LIT000944599
NPCLSV_LIT000949300
NPCLSV_LIT000952700
NPCLSV_LIT000952706
NPCLSV_LIT000953187
NPCLSV_LIT000985654
NPCLSV_LIT001006782
NPCLSV_LIT001007778
NPCLSV_LIT001008511
NPCLSV_LIT001012995
NPCLSV_LIT001032821
NPCLSV_LIT001052705
NPCLSV_LIT001072423
NPCLSV_LIT001101766
NPCLSV_LIT001102058
NPCLSV_LIT001103337
NPCLSV_LIT001103502
NPCLSV_LIT001107949
NPCLSV_LIT001108690
NPCLSV_LIT001109955
NPCLSV_LIT001133980
NPCLSV_LIT001133981
NPCLSV_LIT001139403
NPCLSV_LIT001139695
NPCLSV_LIT001143216
NPCLSV_LIT001145664
NPCLSV_LIT001153638
NPCLSV_LIT001154253
NPCLSV_LIT001154254
NPCLSV_LIT001157640
NPCLSV_LIT001174206
NPCLSV_LIT001186012
NPCLSV_LIT001188166
NPCLSV_LIT001188168
NPCLSV_LIT001205035
NPCLSV_LIT001205990
NPCLSV_LIT001206257
NPCLSV_LIT001223792
NPCLSV_LIT001228309
NPCLSV_LIT001249576
NPCLSV_LIT001285022
NPCLSV_LIT001304460
NPCLSV_LIT001307912
NPCLSV_LIT001332252
NPCLSV_LIT001332254
NPCLSV_LIT001355469
NPCLSV_LIT001358680
NPCLSV_LIT001358682
NPCLSV_LIT001358805
NPCLSV_LIT00136541
NPCLSV_LIT001395475
NPCLSV_LIT001395476
NPCLSV_LIT001406037
NPCLSV_LIT001434422
NPCLSV_LIT001443413
NPCLSV_LIT001443898
NPCLSV_LIT001457530
NPCLSV_LIT001457717
NPCLSV_LIT001463654
NPCLSV_LIT001466349
NPCLSV_LIT001471787
NPCLSV_LIT001480228
NPCLSV_LIT001481757
NPCLSV_LIT001516322
NPCLSV_LIT001537363
NPCLSV_LIT001537756
NPCLSV_LIT001543283
NPCLSV_LIT001543332
NPCLSV_LIT001543360
NPCLSV_LIT001543749
NPCLSV_LIT001573851
NPCLSV_LIT001574840
NPCLSV_LIT001574885
NPCLSV_LIT001574887
NPCLSV_LIT001575354
NPCLSV_LIT001575369
NPCLSV_LIT001575374
NPCLSV_LIT001575398
NPCLSV_LIT001575464
NPCLSV_LIT001577951
NPCLSV_LIT001578414
NPCLSV_LIT001578453
NPCLSV_LIT001579162
NPCLSV_LIT001585631
NPCLSV_LIT001591473
NPCLSV_LIT001638280
NPCLSV_LIT001642990
NPCLSV_LIT001649974
NPCLSV_LIT001650099
NPCLSV_LIT001650157
NPCLSV_LIT001652104
NPCLSV_LIT001657977
NPCLSV_LIT001678259
NPCLSV_LIT001683074
NPCLSV_LIT001699470
NPCLSV_LIT001706519
NPCLSV_LIT001707357
NPCLSV_LIT001715014
NPCLSV_LIT001748615
NPCLSV_LIT001761262
NPCLSV_LIT001768874

NPCLSV_LIT001791936
NPCLSV_LIT001805129
NPCLSV_LIT001824928
NPCLSV_LIT001843954
NPCLSV_LIT001843955
NPCLSV_LIT001845101
NPCLSV_LIT001846507
NPCLSV_LIT001849478
NPCLSV_LIT001850422
NPCLSV_LIT001861118
NPCLSV_LIT001881040
NPCLSV_LIT001897258
NPCLSV_LIT001903939
NPCLSV_LIT001916746
NPCLSV_LIT001924305
NPCLSV_LIT001924306
NPCLSV_LIT001934809
NPCLSV_LIT001984519
NPCLSV_LIT001989585
NPCLSV_LIT001989750
NPCLSV_LIT002016755
NPCLSV_LIT002016756
NPCLSV_LIT002071609
NPCLSV_LIT002213566
NPCLSV_LIT002335921
NPCLSV_LIT002343832
NPCLSV_LIT002348643
NPCLSV_LIT002399206
NPCLSV_LIT002411963
NPCLSV_LIT002414756
NPCLSV_LIT002414759
NPCLSV_LIT002435002
NPCLSV_LIT002449642
NPCLSV_LIT002459751
NPCLSV_LIT002459797
NPCLSV_LIT002469101
NPCLSV_LIT002505721
NPCLSV_LIT002519896
NPCLSV_LIT002529898
NPCLSV_LIT002534934
NPCLSV_LIT002585505
NPCLSV_LIT002608181
NPCLSV_LIT002608182
NPCLSV_LIT002639724
NPCLSV_LIT002641278
NPCLSV_LIT002730179
NPCLSV_LIT002786299
NPCLSV_LIT002789426
NPCLSV_LIT002789427
NPCLSV_LIT002798222
NPCLSV_LIT002865104
NPCLSV_LIT002933453
NPCLSV_LIT002942706
NPCLSV_LIT002946162
NPCLSV_LIT002953493
NPCLSV_LIT002983604
NPCLSV_LIT002990957
NPCLSV_LIT003047243
NPCLSV_LIT003059121
NPCLSV_LIT003063452
NPCLSV_LIT003067251
NPCLSV_LIT003128509
NPCLSV_LIT003194782
NPCLSV_LIT003206131
NPCLSV_LIT003206178
NPCLSV_LIT003211113
NPCLSV_LIT003211354
NPCLSV_LIT003228395
NPCLSV_LIT003250725
NPCLSV_LIT003250727
NPCLSV_LIT003266630
NPCLSV_LIT003296867
NPCLSV_LIT003297197
NPCLSV_LIT003297464
NPCLSV_LIT003315304
NPCLSV_LIT003327984
NPCLSV_LIT003334377
NPCLSV_LIT003354719
NPCLSV_LIT003373745
NPCLSV_LIT003373918
NPCLSV_LIT003377303
NPCLSV_LIT003377415
NPCLSV_LIT003377421
NPCLSV_LIT003377437
NPCLSV_LIT003383021
NPCLSV_LIT003383023
NPCLSV_LIT003396884
NPCLSV_LIT003461575
NPCLSV_LIT003486097
NPCLSV_LIT003514675
NPCLSV_LIT003593797
NPCLSV_LIT003596748
NPCLSV_LIT003602748
NPCLSV_LIT003603020
NPCLSV_LIT003603021
NPCLSV_LIT003617880
NPCLSV_LIT003633681
NPCLSV_LIT003758610
NPCLSV_LIT003822146
NPCLSV_LIT003833399
NPCLSV_LIT003863825
NPCLSV_LIT003976273
NPCLSV_LIT003980770
NPCLSV_LIT004039602
NPCLSV_LIT004054309
NPCLSV_LIT004060598
NPCLSV_LIT004308066
NPCLSV_LIT004335354
NPCLSV_LIT004438397
NPCLSV_LIT004459338
NPCLSV_LIT004561916
NPCLSV_LIT004598758
NPCLSV_LIT004606568
NPCLSV_LIT004647755
NPCLSV_LIT004663617
NPCLSV_LIT004685255
NPCLSV_LIT004726871
NPCLSV_LIT004892137
NPCLSV_LIT004997261
NPCLSV_LIT005028243
NPCLSV_LIT005096190
NPCLSV_LIT005110062
NPCLSV_LIT005163837
NPCLSV_LIT005214117
NPCLSV_LIT005264626
NPCLSV_LIT005301422

NPCLSV_LIT005376864
NPCLSV_LIT005412660
NPCLSV_LIT005412664
NPCLSV_LIT005415164
NPCLSV_LIT005464479
NPCLSV_LIT005475770
NPCLSV_LIT005549841
NPCLSV_LIT005605316
NPCLSV_LIT005737982
NPCLSV_LIT005740872
NPCLSV_LIT005770886
NPCLSV_LIT005822957
NPCLSV_LIT005836160
NPCLSV_LIT005839541
NPCLSV_LIT005897995
NPCLSV_LIT005952312
NPCLSV_LIT006220667
NPCLSV_LIT006220893
NPCLSV_LIT006221500
NPCLSV_LIT006246902
NPCLSV_LIT006250261
NPCLSV_LIT006260050
NPCLSV_LIT006264511
NPCLSV_LIT006272553
NPCLSV_LIT006272935
NPCLSV_LIT006273285
NPCLSV_LIT006274514
NPCLSV_LIT006274542
NPCLSV_LIT006274542
NPCLSV_LIT006282309
NPCLSV_LIT006289452
NPCLSV_LIT006289815
NPCLSV_LIT006321788
NPCLSV_LIT006346213
NPCLSV_LIT006348856
NPCLSV_LIT006355928
NPCLSV_LIT006358466
NPCLSV_LIT006358467
NPCLSV_LIT006358479
NPCLSV_LIT006358480
NPCLSV_LIT006367817
NPCLSV_LIT006367969
NPCLSV_LIT006385827
NPCLSV_LIT006385893
NPCLSV_LIT006390259
NPCLSV_LIT006391466
NPCLSV_LIT006408894
NPCLSV_LIT006420838
NPCLSV_LIT006427694
NPCLSV_LIT006429966
NPCLSV_LIT006438391
NPCLSV_LIT006447423
NPCLSV_LIT006502449
NPCLSV_LIT006510138
NPCLSV_LIT006523388
NPCLSV_LIT006523603
NPCLSV_LIT006544897
NPCLSV_LIT006578253
NPCLSV_LIT006578255
NPCLSV_LIT006578302
NPCLSV_LIT006578320
NPCLSV_LIT006578325
NPCLSV_LIT006578329
NPCLSV_LIT006588883
NPCLSV_LIT006592027
NPCLSV_LIT006612017
NPCLSV_LIT006616715
NPCLSV_LIT006628848
NPCLSV_LIT006649975
NPCLSV_LIT006657218
NPCLSV_LIT006673162
NPCLSV_LIT006673194
NPCLSV_LIT006675415
NPCLSV_LIT006675591
NPCLSV_LIT006677304
NPCLSV_LIT006678171
NPCLSV_LIT006684949
NPCLSV_LIT006701918
NPCLSV_LIT006720842
NPCLSV_LIT006743740
NPCLSV_LIT006744069
NPCLSV_LIT006752498
NPCLSV_LIT006755023
NPCLSV_LIT006756665
NPCLSV_LIT006767366
NPCLSV_LIT006767367
NPCLSV_LIT006773945
NPCLSV_LIT006776069
NPCLSV_LIT006777725
NPCLSV_LIT006778114
NPCLSV_LIT006781235
NPCLSV_LIT006806981
NPCLSV_LIT006815196
NPCLSV_LIT006820701
NPCLSV_LIT006834049
NPCLSV_LIT006835576
NPCLSV_LIT006836038
NPCLSV_LIT006836039
NPCLSV_LIT006840964
NPCLSV_LIT006845178
NPCLSV_LIT006847061
NPCLSV_LIT006855399
NPCLSV_LIT006859265
NPCLSV_LIT006859342
NPCLSV_LIT006900292
NPCLSV_LIT006900307
NPCLSV_LIT006906294
NPCLSV_LIT006911272
NPCLSV_LIT006987971
NPCLSV_LIT007057690
NPCLSV_LIT007057707
NPCLSV_LIT007063328
NPCLSV_LIT007065670
NPCLSV_LIT007070934
NPCLSV_LIT007071287
NPCLSV_LIT007088907
NPCLSV_LIT007088908
NPCLSV_LIT007106922
NPCLSV_LIT007134026
NPCLSV_LIT007161966
NPCLSV_LIT007177967
NPCLSV_LIT007193934
NPCLSV_LIT007193937
NPCLSV_LIT007208934
NPCLSV_LIT007212685
NPCLSV_LIT007212768

NPCLSV_LIT007224560	NPCLSV00014620	NPCLSV00022651
NPCLSV_LIT007252180	NPCLSV00017892	NPCLSV00022824
NPCLSV_LIT007252203	NPCLSV00018194	NPCLSV00022832
NPCLSV_LIT007252205	NPCLSV00022315	NPCLSV00022849
NPCLSV00014370	NPCLSV00022425	NPCLSV02655466
NPCLSV00014433	NPCLSV00022516	NPCLSV02655467